Ameridose, LLC – Application for a New Store – 50 Fountain Street (2006) DATE: STOTED STILL ROWS DATE: STOTED SATES TO COMPINE THE PERSON TO PERSON TO SOUTH PERSON TO THE P



The Commonwealth of Massachusetts
Executive Office of Health and Human Service
Department of Public Health
Division of Health Professions Licensure

Board of Registration in Pharmacy 239 Causeway Street, Suite 200, 2nd Floor Boston, MA 02114 (800) 414-0168 (office) / 617-973-0983 (fax) http://www.mass.gov/reg/boards/ph

APPLICATION FOR A NEW STORE

MTT ROMNEY GOVERNOR

KERRY HEALEY
LIEUTENANT GOVERNOR

TIMOTHY R. MURPHY SECRETARY

PAUL J. COTE, JR. COMMISSIONER

PERCEPORTIKAS

APR 25 2006

BOARD OF PHARMACY

I hereby apply for a permit to operate a store for the transaction of retail drug business in accordance with the provisions of Chapter 112, General Laws.

\$351.00 licensure / application fee. Make check or money order for \$351.00 payable to the Commonwealth of Massachusetts. This fee is non-refundable.

- 1. Legal Name of Business. Ameridose, LLC
- 2. Full Business Address (Street Address, City, State and Zip). 50 Fountain Street, Framingham, MA 01702
- 3. Area Code and Telephone Number. 508-656-2653
- 4. All trade or business names ("D.B.A." names) used by same Corporation or by License. Ameridose, LLC
- 5. Type of ownership or operation (i.e., sole proprietorship, partnership, corporation). Limited Liability Company (LLC)

If corporation, please submit articles of corporation. Please see Attachment "A"

5. Names(s) and Social Security Number(s) of the owner(s) and/or operator(s) of the licensee. Please indicate type of ownership - Partnerships: the name of each partner and name address of partnership;

Corporations: the name and title of each corporate officer and director, the corporate names, name and address of parent company, if any, and the State of incorporation; Sole Proprietorship: the name of the sole proprietor and the address of the business entity. Please see Attachment "B"

- 7. Name of registered pharmacist charged with the management of the pharmacy. Sophia Pasedis, RPh, PharmD.
- 8. Registration number of above manager. 20217
- 9. Name(s) and registration number(s) of staff pharmacist(s) employed at pharmacy. Sophia Pasedis, RPh, PharmD.
- 10. Have any of the applicant(s) and/or managers-in-charge had: 1) any convictions related to the distribution of drugs (including samples); 2) any felony convictions; 3) any suspension(s) or revocation(s) or other sanction(s) by federal, state or local governmental agency of any license or registration currently or previously held by the applicant or license for the manufacture, distribution, or dispensing of any drugs, including controlled substances? NO

Have any applications for licensure been denied by any federal or state agency including any state board of pharmacy? **NO**

List and explain. Attach additional sheets if necessary. N/A

- 11. The applicant/licensee must notify the Board in writing of any changes in ownership or management within thirty (30) days of such change(s).
- 12. Social Security Number (Mandatory).

 Pursuant to M.G.L. c. 62C, s. 47A, the Division of Registration is required to obtain your social security number and forward it to the Department of Revenue. The Department of Revenue will use your social security number to ascertain whether you are in compliance with the tax laws of the Commonwealth.

List any licenses/certifications you hold in the United States or any country or foreign jurisdiction and the state/jurisdiction from which the license/certification was originally issued. Please attach a certificate of standing from each state or jurisdiction in which you are licensed/certified, indicating the status of your license and any relevant disciplinary information. Massachusetts Registered Pharmacist License #20217, Attachment "C."

- 14. Has any disciplinary action been taken against you by a licensing/certification board located in the United States or any country or foreign jurisdiction? Yes: ☐ No: X

 If yes, please state the details (use a separate sheet if necessary). N/A
- 15. Are you the subject of pending disciplinary actions by a licensing/certification board located in the United States or any country or foreign jurisdiction? Yes: □ No: X
 If yes, please state the details (use a separate sheet if necessary). N/A
- 16. Have you ever voluntarily surrendered or resigned a professional license to a licensing/certification board in the United States or any country or foreign jurisdiction? Yes: □ No: X If yes, please state the details (use a separate sheet if necessary). N/A
- 17. Have you ever applied for and been denied a professional license in the United States or any country or foreign jurisdiction? Yes: □ No: X

 If yes, please state the details (use a separate sheet if necessary). N/A

18. Pursuant to Board Regulations at 247CMR δ 6.01(3), The Board shall not register nor permit ownership of a pharmacy or pharmacy department by a practitioner with prescriptive privileges. By signing this application the applicant certifies that none of the owners, directors or officers have prescriptive privileges.

Affidavit (must be completed and notarized)

Social Security Number of the Manager of Record

Pursuant to M.G.L. c. 62C, s. 49A, I certify under the penalties of perjury that I, to the best of my knowledge and belief, have filed all state tax returns and paid all state taxes required under law.

The applicant certifies that each person employed in any prescription drug distribution activity has the education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety, and security will at all times be maintained as required by law.

I hereby state that I am t	_	~		ensure; that all	statement	ts are true and
correct in all respects an	d are made under	the penalties of pe	rjury.			
	+ Acad			<u>.</u>		
Signature of pharma	cist who is to man	nage the pharmacy	or pharmacy depa	ertment		
14 ·			· .	•		
April/5, 2006 Date						
				•	•	

Sworn and subscribed before me this 14th day of April, 2006

My commission expires 12/31/2010. Cauce fee Security

Notary Public

To be completed by the Board: Check \$ 351 Date 5/06 Number 6170

Received

APR 25 2006

BOARD OF PHARMACY

Application for Registration to Manage and Operate a New Community Pharmacy

Ameridose, LLC 50 Fountain Street Framingham, MA 01702 508-656-2653

fax 508-872-0044



MITT ROMNEY GOVERNOR

KERRY HEALEY
LIEUTENANT GOVERNOR

TIMOTHY R. MURPHY SECRETARY

PAUL J. COTE, JR. COMMISSIONER

JEAN K. PONTIKAS DIRECTOR

The Commonwealth of Massachusetts Executive Office of Health and Human Services Department of Public Health Division of Health Professions Licensure

Board of Registration in Pharmacy 239 Causeway Street, Suite 200, 2nd Floor Boston, MA 02114 (800) 414-0168 (office) / 617-973-0983 (fax) http://www.mass.gov/reg/boards/ph

APPLICATION FOR REGISTRATION TO MANAGE AND OPERATE A NEW COMMUNITY PHARMACY

- (1) In order to be registered by the Board to manage and operate a pharmacy or pharmacy department and be issued a permit to do so, the registered pharmacist who shall be responsible for the management and operation of the pharmacy or pharmacy department shall obtain and submit to the Board an application for registration to manage and operate a pharmacy or pharmacy department available from the Board. A completed application shall be:
 - (a) fully and properly completed and signed, under the penalties of perjury, by the pharmacist who is to manage and operate the pharmacy or pharmacy department;
 - (b) accompanied by a statement of the scheduled hours during which the pharmacy or pharmacy department is to remain open, including the time of opening and closing during regular business hours for each day of the week; Attachment "D"
 - (c) accompanied by an application, available from the Board, for a Massachusetts controlled substance registration;
 - (d) accompanied by an application, available from the Board, for a certificate of fitness, if applicable;
 - (e) accompanied by a check or money order made payable, in the proper amount, to the "Commonwealth of Massachusetts Board of Registration in Pharmacy"; and
 - (f) accompanied by any additional information as determined by the Board.
 - (g) accompanied by an official blueprint or certified architectural plans drawn to scale clearly designating both the prescription and patient consultation areas (pharmacy department shall be outlined in <u>RED</u>).
- (2) A completed application to operate a pharmacy shall include:
 - (a) a copy of the corporation's Articles of Organization, signed and sealed by the Secretary of State if the corporation is incorporated in the Commonwealth;

(b) a copy of the corporation's Foreign Corporation Certificate, signed and sealed by the Secretary of State pursuant to M.G.L. c. 181, § 4, if the corporation in incorporated in another state; (c) a statement of the name and address of each officer and director of the corporation and the position held; nla (d) the d/b/a name of the corporation; and (f) if the corporation is not publicly owned, the total amount and type of stock issued to each stockholder and the names and addresses of said stockholder(s). (3) The Board shall not register nor permit ownership of a pharmacy or pharmacy department by a practitioner with prescriptive privileges. (4) Before acting upon any application for registration to manage and operate a pharmacy or pharmacy department, the Board may require a hearing and, if requested to do so, the applicant shall personally appear before the Board to answer questions to enable the Board to determine that issuance of a permit would be in the best interests of the public health, welfare and safety as set forth in M.G.L. c. 112, § 39. (5) The Board may require an inspection of the pharmacy or pharmacy department before final approval of the application is granted. All proposed pharmacies and pharmacy departments shall comply with the following requirements: (a) No application for registration to manage and operate a pharmacy or pharmacy department shall be approved unless, upon inspection, the following is maintained on the pharmacy premises: 1. a current copy or electronic version of the Massachusetts List of Interchangeable Drugs (MLID), including the Orange Book, Additional List, Exception List, and the latest supplements thereto; 2. a current copy or electronic version (with quarterly updates) of a compendia appropriate to the practice setting approved by the pharmacist manager of record. 3. a current copy or electronic version of Board Regulations 247 CMR 1.00 et seq.; 4. a balance capable of accurately weighing quantities as small as 13 milligrams, which balance shall be tested and sealed by the state or local sealer of weights and measures annually; 5. the equipment necessary to conduct the practice of pharmacy according to the standards set forth by most current edition of the United States Pharmacopoeia; 6. prescription labels which bear the name and address of the proposed pharmacy;

7. appropriate sanitary appliances, including a suitable sink which shall be equipped for hot and cold running water and which shall be situated in or near the area in which

prescriptions are to be filled;

- 8. whenever applicable, at least one bound book for recording sales of controlled substances which may be sold over-the-counter without a prescription; and
- 9. whenever applicable, at least one book for recording sales of alcoholic beverages and signatures of the purchasers of these beverages.
- (b) There shall be within every pharmacy or pharmacy department a prescription area of not less than 300 square feet to accommodate the appropriate pharmaceutical equipment, apparatus, and supplies, and to facilitate the proper preparation and compounding of prescribed medications. This area shall provide for an arrangement and storage of drugs that is calculated to prevent their accidental misuse.
- (c) Any pharmacy or pharmacy department which establishes a central intravenous admixture service (CIVAS) shall, in addition to the 300 square feet required by 247 CMR 6.01(6)(b), provide for a separate room referred to as a "clean room" apart from all other areas of the pharmacy or pharmacy department. This clean room shall meet the following requirements:
- 1. There shall be a minimum working area of 72 square feet;
- 2. it shall be closed on all sides except for a door and an opening to allow for the passage of materials;
- 3. it shall have a laminar flow hood with either vertical or horizontal air flow;
- 4. the laminar flow hood standards of operation of HEPA (High Energy Particulate Air) filters and prefilters must be determined and certification shall be made annually by a Board-approved hood certification service;
- 5. the Board shall be notified before beginning operation of the clean room to verify hood certification;
- 6. the area of the clean room shall be under continual positive pressure unless the hood is self-venting; and
- 7. applications for construction of a pharmacy with a clean room received after September 30, 1996 shall show the clean room located directly adjacent to the prescription area/department.
- (d) Patient Consultation Area.
- 1. A pharmacy must provide a designated consultation area, with signage stating "Patient Consultation Area", designed to provide adequate privacy for confidential visual and auditory patient counseling. The private consultation area must be accessible by a patient from the outside of the prescription dispensing area without having to traverse a stockroom or the prescription dispensing area.
- 2. 247 CMR 6.01(5)(d) shall be effective for all new or relocating pharmacies on April 1, 2005. All existing pharmacies must comply with 247 CMR 6.01(5)(d) by January 1, 2007.

- (6) The Board shall issue a permit indicating the pharmacy or pharmacy department's registration number if the Board finds, in its reasonable discretion, that approving the application would be consistent with the best interest of public health, welfare and safety.
- (7) All fees submitted to the Board in connection with an application for registration to operate a pharmacy or pharmacy department, which are reviewed and acted upon by the Board, are nonrefundable.

Please be advised that no pharmacy and pharmacy department shall begin to operate until the application has been approved by the Board and: 1) the pharmacist Manager of Record has received from the Board a permit number to manage and operate the pharmacy and or pharmacy department, and 2) has received a controlled substances registration number.

For complete information regarding relocation regulations, please refer to 247 CMR 6.01 & 6.02. If additional information is necessary, please contact the Board office at (800) 414-0168.

To obtain a DEA number, please contact the Drug Enforcement Administration (DEA) office for an application. The address is: J.F.K. Federal Building

Drug Enforcement Administration Room E400 15 New Sudbury Court Boston, MA 02203-0131 (617) 557-2200



Attachment "A" The Commonwealth of Massachusetts

Secretary of the Commonwealth

State House, Boston, Massachusetts 02133

April 10, 2006

TO WHOM IT MAY CONCERN:

I hereby certify that a certificate of organization of a Limited Liability Company was filed in this office by

AMERIDOSE, LLC

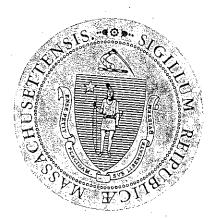
in accordance with the provisions of Massachusetts General Laws Chapter 156C on February 8, 2006.

I further certify that said Limited Liability Company has filed all annual reports due and paid all fees with respect to such reports; that said Limited Liability Company has not filed a certificate of cancellation or withdrawal; and that, said Limited Liability Company is in good standing with this office.

I also certify that the names of all managers listed in the most recent filing are: GREGORY CONIGLIARO, BARRY J. CADDEN

I further certify, the names of all persons authorized to execute documents filed with this office and listed in the most recent filing are: GREGORY CONIGLIARO, BARRY J. CADDEN

The names of all persons authorized to act with respect to real property listed in the most recent filing are: GREGORY CONIGLIARO, BARRY J. CADDEN



In testimony of which, I have hereunto affixed the Great Seal of the Commonwealth on the date first above written.

William Travino Galecin

Secretary of the Commonwealth

Processed By:MT

AMERIDOSE, LLC CERTIFICATE OF ORGANIZATION

FEB 3 8 2006

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SECRETARY OF THE CONTRACTOR

COPY FIX OF THE MADE

Pursuant to the provisions of the Massachusetts Limited Liability Company Act (the "Act") the undersigned hereby certifies as follows:

- 1. <u>Name of the Limited Liability Company.</u> The name of the limited liability company formed hereby (the "Company") is Ameridose, LLC.
- 2. Office of the Limited Liability Company. The address of the office of the Company in the Commonwealth required to be maintained by Section 5 of the Act is 50 Fountain Street, Framingham, MA 01702.
- 3. Agent for Services of Process. The name and address of the resident agent for services of process for the Company is Gregory Conigliaro, 50 Fountain Street, Framingham, MA 01702.
 - 4. <u>Date of Dissolution.</u> The Company is to have no specific date of dissolution.
 - 5. Manager. The Managers are:

Gregory Conigliaro 50 Fountain Street Framingham, MA 01702

Barry J. Cadden 50 Fountain Street Framingham, MA 01702

- 6. <u>Execution of Documents.</u> Either Manager is authorized to execute any documents to be filed with the Secretary of State of the Commonwealth of Massachusetts.
 - 7. <u>Business of the Company.</u>
 - (a) To provide unit dose repackaging services;
 - (b) To exercise all other powers necessary to or reasonably connected with the Company's business that may be legally exercised by limited liability companies under the Act; and
 - (c) To engage in all activities necessary, customary, convenient, or incident to any of the foregoing.
 - 8. Execution of Documents Relating to Real Property. Either Manager is authorized

to execute, acknowledge, deliver and record any recordable instrument on behalf of the Company purporting to affect any interest in real property, whether to be recorded with a registry of deeds or a district office of the Land Court.

IN WITNESS WHEREOF, the undersigned hereby affirms under the penalties of perjury that the facts stated herein are true, this _6_ day of February, 2006.

Chega a Conflicto
Gregor Conigliaro

Check/Voucher#	<i>‡ 89</i>
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The Commonwealth of Massachusetts Limited Liability Company (General Laws, Chapter 156C)

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Filed this 8 day February, 2006

aple Francis Gallet

William Francis Galvin Secretary of the Commonwealth

Name Jonathan D Tamkin

Phone 617 964 2501

Attachment "B"

Ameridose, LLC

50 Fountain Street, Framingham, MA 01702 Tel: 508-656-2653

Fax: 508.872-0044

TYPE OF OWNERSHIP

Limited Liability Company
Organized in the Commonwealth of Massachusetts

COMPANY OPERATORS/MANAGERS

1. Gregory A. Conigliaro, Manager



2. Barry J. Cadden, R. Ph., Manager



LLC OWNERS

1. Carla R. Conigliaro
Ownership: 55% membership interest

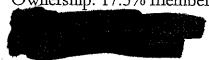


2. Barry J. Cadden, R. Ph.

Ownership: 17.5% membership interest



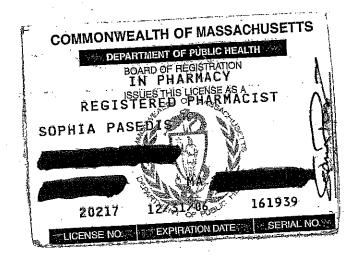
3. Lisa M. Conigliaro Cadden, R. Ph. Ownership: 17.5% membership interest



4. Gregory A. Conigliaro

Ownership: 10% membership interest

Attachment "C"



DPH CONTROL # 0259680

IMPORTANT

If this license becomes lost or destroyed, notify your Board at the: Department of Public Health, 239 Causeway St., 5th Floor, Boston, MA 02114

Fryour name or address change, notify your Board to insure the proper mailing of your next Renewal Application. Always refer to your license number when corresponding with your Board. This license is subject to the provisions of the General Laws as amended. It is a privilege, and cannot be loaned or assigned to any other entity. Keep this license on your person, posted, or as required by law.

Please visit our web site at: http://mass.gov/dph/boards

· Salar



The Commonwealth of Massachusetts

Attachment "D"

Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure

MITT ROMNEY GOVERNOR

KERRY HEALEY LIEUTENANT GOVERNOR

TIMOTHY R. MURPHY SECRETARY

PAUL J. COTE, JR. COMMISSIONER

JEAN K. PONTIKAS DIRECTOR Board of Registration in Pharmacy 239 Causeway Street, Suite 200, 2nd Floor Boston, MA 02114

(800) 414-0168 (office) / 617-973-0983 (fax) http://www.mass.gov/reg/boards/ph

PHARMACY HOURS

Name of Store: Ameridose, LLC

Street: 50 Fountain Street

City or Town: Framingham Zip Code: 01702

Phone Number: <u>508-656-2653</u>

	Open	Close	Hours
Monday	8:30 am	5:30 pm	9
Tuesday	8:30 am	5:30 pm	9
Wednesday	8:30 am	5:30 pm	9
Thursday	8:30 am	5:30 pm	9
Friday	8:30 am	5:30 pm	9
Saturday	Closed	Closed	0
Sunday	Closed	Closed	0

45

Total Hours Per Week:

April 14, 2006

Date

Signature of Manager of Record or Duly Authorized Representative

Sophia Pasedis, RPh, PharmD.

Print Full Name

Application for Certificate of Fitness

Received

APR 25 2006

BOARD OF

Ameridose, LLC

50 Fountain Street Framingham, MA 01702 508-656-2653 fax 508-872-0044



MITT ROMNEY GOVERNOR

KERRY HEALEY
LIEUTENANT GOVERNOR

TIMOTHY R. MURPHY SECRETARY

PAUL J. COTE, JR.

JEAN K. PONTIKAS DIRECTOR

The Commonwealth of Massachusetts

Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure

Board of Registration in Pharmacy 239 Causeway Street, Suite 200, 2nd Floor Boston, MA 02114

(800) 414-0168 (office) / 617-973-0983 (fax)

http://www.mass.gov/reg/boards/ph

APR 25 2006.

Received

BOARD OF PHARMACY

APPLICATION FOR A CERTIFICATE OF FITNESS Manager of Record Must Complete Application. Fee: \$120.00

I, Sophia Pasedis (name), at 508-656-2653 (telephone), of 50 Fountain Street (street address), Framingham (city), MA (state), 01702 (zip code), a registered pharmacist, certificate number 20217 being now actively engaged in conducting a retail drug business as sole owner or Manager of Record for the firm / corporation of Ameridose, LLC do hereby apply for CERTIFICATE OF FITNESS, claiming to be a proper person to be entrusted with the authority to:

- 1) Use alcohol for the manufacture of United States Pharmacopeia and National Formulary preparations and all medicinal preparations unfit for beverage purposes,
- 2) Sell, in accordance with the laws of the Commonwealth, alcohol and alcoholic liquors, and that the public good will be promoted by the granting of such license.

I have <u>\$0</u> (give dollar amount) invested in said retail business and will comply with the laws of this Commonwealth and the regulations of the Board relating to the use and sale of the alcohol and alcoholic liquors.

I certify that I have not been convicted of a violation of said laws within one year prior to the date of this application.

I agree to notify the board at once if I cease to conduct the retail drug business at the above location and will return the certificate issued thereon.

Signed Sedu tasey

Date: <u>April 14, 2006</u>

Please submit non-refundable check or money order for \$120.00 payable to the Commonwealth of Massachusetts.

	- Please do not write below this line -	
Check / J D Number 980	M.O Date 5/2/06	

Application for Mass. Controlled Substance Registration

Received

APR 25 2006

BOARD OF PHARMACY

Ameridose, LLC 50 Fountain Street Framingham, MA 01702 508-656-2653 fax 508-872-0044



MITT ROMNEY GOVERNOR

KERRY HEALEY
LIEUTENANT GOVERNOR

TIMOTHY R. MURPHY SECRETARY

PAUL J. COTE, JR. COMMISSIONER

JEAN K. PONTIKAS DIRECTOR

The Commonwealth of Massachusetts

Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure

Board of Registration in Pharmacy 239 Causeway Street, Suite 200, 2nd Floor Boston, MA 02114 (800) 414-0168 (office) / 617-973-0983 (fax) Received http://www.mass.gov/reg/boards/ph

BOARD OF PHARMACY

APPLICATION FOR MASS. CONTROLLED SUBSTANCE REGISTRATION FEE: \$151.00

Cash	Check # /K/			
No	Date 5/2/06	M.O		
	Please do not write above tl	is line		
I here apply for Registration un	nder Mass. Controlled Substances	Act-M.G.L. 94C Sect	ion 7.	
Applicant Name (corporation)	Ameridose, LLC			
Business Address:	50 Fountain Street (No. and Street)			
	Framingham, MA 01702			
	(City or Town)	(State)	(Zip Code)	
Registration Classification: (a) X	Retail Drug Store (b)	Who	olesale/Mfg/Dist.	
(c)	Hospital/Clinic/Inst. (d)	N	uclear	

FEIN # 20-4253511

•						
Schedule II	Schedule III	(X) Schedule IV	(X) Schedule V	(X) Schedule	VI	
(X) Non-Narcotic	(X) Non-Narcot	tic	4			
(X) Narcotic	(X) Narcotic					
Current drugstore p	ermit No. pending	Current V	Vholesale Druggist 1	License No	n/a	
Signature of Applie	cant Me	es a Cons	Haw, u	ige.		
	0		f facility must sign a	application)		7,

Please submit check or money order for \$151.00 payable to the Commonwealth of Massachusetts.

WARNING:

Drug Schedule

In accordance with Chapter 94 M.G.L. Sec 13, the Board of Registration in Pharmacy in the case of a retail drug business or wholesale druggist, may suspend or revoke a registration to manufacture, distribute, dispense or possess a controlled substance after a hearing pursuant to the provisions of Chapter 34A and upon finding that the registrant has furnished false or fraudulent information in any application filed under the provisions of Chapter 94C.

Ameridose, LLC

50 Fountain Street, Framingham, MA 01702 508-656-2653, fax 508-872-0044

April 25, 2006

Charles R. Young

Executive Director

Received

Massachusetts Board of Registration in Pharmacy

239 Causeway St

APR 25 2006

Boston, MA 02113

BOARD OF

Dear Mr. Young,

PHARMACY

Please find attached our Application for Registration to Manage and Operate a New Community Pharmacy as well as supporting applications and drawings.

We are confident that our services will fill an urgent need in the Massachusetts healthcare environment and enhance public health, welfare and safety.

I may be reached at 508-656-2633 should you require further information. Thank you for your consideration.

Sincerely,

AMERIDOSE, LLC.

Gregory A. Conigliaro

Manager

Received

APR 25 2006

BOARD OF PHARMACY

Petition for a Waiver of the Provisions of 247 Licensure of a Pharmacy and or Pharmacy Department

Ameridose, LLC 50 Fountain Street Framingham, MA 01702 508-656-2653 fax 508-872-0044



MITT ROMNEY GOVERNOR

KERRY HEALEY
LIEUTENANT GOVERNOR

TIMOTHY R. MURPHY SECRETARY

PAUL J. COTE, JR. COMMISSIONER

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Board of Registration In Pharmacy
239 Causeway Street, Suite 200, Boston, MA 02114.
(800) 414-0168 (office) / 617-973-0983 (fax) eceived
http://www.mass.gov/reg/boards/ph

BUARD OF PETITION FOR A WAIVER OF THE PROVISIONS OF 247 HARMACY LICENSURE OF A PHARMACY AND OR PHARMACY DEPARTMENT

Application to be completed by the registered pharmacist who is or shall be responsible for the management and operation of the pharmacy and or pharmacy department.

Pursuant to 247 CMR (14.01), I hereby apply for a special or limited use pharmacy or pharmacy department permit because the type of pharmacy practice is of a special, limited or unusual nature as compared to regular pharmacy services.

Name of pharmacy and or pharmacy department: Ameridose, LLC

Location: 50 Fountain Street, Framingham, MA 01702

Phone number: 508-656-2653

Contact Person: Sophia Pasedis, RPh, PharmD

Please use separate sheets to complete the following and attach sheets to application:

- 1. List the regulatory requirements(s) for which a waiver is requested and provide an explanation as to why each regulation should not apply to the pharmacy/pharmacy department.
- 2. Explain the compelling public interest that would be served by the granting of a waiver.
- 3. Explain why adherence to the regulation(s) would be impractical and unduly burdensome.
- 4. Include a comprehensive statement of the policies and procedures of the proposed operation, including safeguards to protect the public health, welfare and safety.

Before acting upon any petition the Board may require the applicant to personally appear before the Board to answer questions that would enable the Board to determine that the issuance of a permit would be in the best interest of the public health, welfare and safety and adherence to 247 CMR would be unreasonable.

Upon the granting of a waiver and issuance of a special or limited-use permit, the Board will issue a written finding that recites the specific Board regulations(s) which are being waived, the reasons the Board is waiving the regulation(s) at issue, and lists and contingent restrictions under which the pharmacy or pharmacy department may operate.

I declare that the statement and answered herein-contained are true and are made under the pains and penalties of perjury.

Signature of pharmacist manager of record

Date

Petition for a Waiver of the Provisions of 247 Licensure of a Pharmacy and or Pharmacy Department

1. List the regulatory requirements(s) for which a waiver is requested and provide an explanation as to why each regulation should not apply to the pharmacy/pharmacy/department.

247 CMR 6.02 (4) – The pharmacy or pharmacy department shall maintain on premise at all times a sufficient variety and supply of medicinal chemicals and preparations which are necessary to compound and dispense commonly prescribed mediations in accordance with the usual needs of the community

We are requesting a waiver to the above provision. It is our opinion that Ameridose's pharmacy practice is of a special limited or unusual nature compared to the regular retail pharmacy.

2. Explain the compelling public interest that would be served by the granting of a waiver.

Ameridose serves the public interest by offering high quality sterile IV admixtures, TPNs and repackaging services to hospital pharmacy departments, clinics and physician's offices - our community. Ameridose will not service the public directly. We do not intend to maintain or dispense all standard prescription medications as may be found in a typical retail pharmacy setting. Rather, we will be a conduit to improved patient care and safety by offering high quality medications to the above entities subject to factors such as beyond use dating and other safety considerations.

The need for our services has spawned from the rapidly changing regulatory environment which the pharmacy departments and clinics are now tasked to manage, including JCAHO and USP requirements. As a result, hospitals and clinics are seeking to outsource these critical services. Our trained registered pharmacists and certified technicians will be able to concentrate on preparing the highest quality medications, while our clients will be freed up to focus on the needs and care of their patients, which is what they do best. The services provided by Ameridose to healthcare institutions, clinics and physicians across the Commonwealth is urgently needed and will absolutely enhance public health, welfare and safety.

3. Explain why adherence to the regulation(s) would be impractical and unduly burdensome.

The regulation in question is impractical and unduly burdensome in this instance - we will be unable to offer all prescription medications typically found in a retail pharmacy and/or available from a wholesaler. Due to the specialized nature of the equipment, facilities and personnel required to provide our unique IV admixture, TPN and repackaging services, the maintenance and dispensing of typical manufactured medications would be incongruent with our mission.

It should be noted, that there are approximately nineteen (19) standard retail pharmacies currently located in Framingham, MA as well as several wholesalers in-state. As such, medications required by the public that we do not plan to dispense at Ameridose are readily available in the local community.

4. Include a comprehensive statement of the policies and procedures of the proposed operation, including safeguards to protect the public health, welfare and safety.

All of our high quality sterile IV admixtures, including TPNs, will be prepared in a controlled environment, using the latest Laminar Flow Technology contained within a state-of-the-art ISO 6 Cleantoom.

Ameridose has developed and shall maintain a complete set of Standard Operating Procedures (SOPs). Chapters include: Guidelines for Preparations, Facilities and Cleaning Procedures, Equipment and Supplies, Pharmacy Practice, Sterilization and Depyrogenation and Quality Assurance/Quality Control. All of these SOPs shall be reviewed and followed by all pharmacists and technicians on an ongoing basis. Ameridose has developed and shall maintain a company-wide Quality Assurance Program. This program shall insure real-time improvements to our operations on a continual basis.

Ameridose's "above and beyond mentality" shall insure that safeguards are always in place to protect the public health, welfare and safety.



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure
239 Causeway Street, 2nd Floor, Boston, MA 02114

MITT ROMNEY GOVERNOR

KERRY HEALEY
LIEUTENANT GOVERNOR

TIMOTHY R. MURPHY PAUL J. COTE, JR. COMMISSIONER

JEAN K. PONTIKAS DIRECTOR



#3467

REQUEST FOR STAFF ASSIGNMENT

Schu letter i	o combiamant: 🖂 🔞	pard to send letter to complainant of outcome:
	(To be filed Out by R	(equestor)
ROARD NAME		•
BOARD NAME (entire):	PHARMACY	
REQUESTED BY: Jame	s D. Coffey, Assoc. Dir.	Date: 05/12/06 James (1)
APPROVED BY:		DATE ASSIGNED:
INVESTIGATOR ASSIG	NED: Emery	DATE ASSIGNED:
Summary of Assignment:	To conduct a contro	olled premises initial inspection of Ameridose,
LLC proposed to be located	at 50 Fountain Street, Fran	ningham, MA 01702 pursuant to a NEW
		ecord of such pharmacy is Sophia Pasedis, R.Ph.,
(Lic. No. 20217). The conta	ct person for such inspectio	on is Sophia Pasedis, R.Ph., MOR (508-656-2653
). The proposed opening dat	e is not indicated on the app	plication. (Investigator shall ensure that a
designated counseling area	is provided prior to related	d approval and that pharmacy is to comply with
company policies for counse	eling. Please distribute the I	Boards Best Practices to the proposed Manager of
Record. **It should be note	d that the Board APPROV	ED the requested WAIVER 6.02(4).
		to the Board to be attached to the application
for licensure prior to grant	ing a final permit number	r.
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rangang sangka kalabida pangkang managan kangalabihan da kalabina na danamat da kalabida perpana da kalabina nanga managa bandak	(To Be Filed Out	By Admin. Staff)

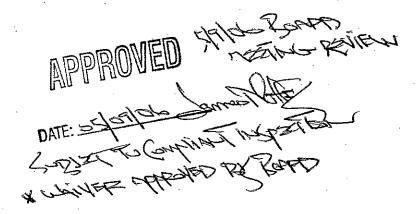


Last Updated: 05/12/2005

The Commonwealth of Massachusetts

Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure
239 Causeway Street, 2nd Floor, Boston, MA 02114

Assignment Number: SABD Code	e: <u>DS</u> 1	ŦΥ: <u></u> Ο(ρ	NO:	095	MAI 17	ZŪ
(To b	e filed out l	by Investi	gator)			
Complainant Name:			-			
Subject of Assignment:	·				•	
Lic #:	•		· ·			
Home Address:			,			
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City, State, Zip:				٠,		
Business Name:				<u> </u>		
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Address:						
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City, State, Zip:		1				
DISPOSITION: C/05Ed	7/13	106		•		
License #	346	<u>7</u>	-			_
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Investigators Initial	ls:	~ —	_			_
Date Completed: 7/13/26 Ti	ime Utilized		3	hrs		
Additional Information attached: Supervisor's signature:	THE STATE OF THE S		Dat	e: 7/26/	Op.	
S:\Pharmacy\STAFF ASSIGNMENTS\ameridose.framingham.may	new.2006.doc)				





The Commonwealth of Massachusetts
Executive Office of Health and Human Service
Department of Public Health
Division of Health Professions Licensure

Board of Registration in Pharmacy 239 Causeway Street, Suite 200, 2nd Floor Boston, MA 02114 (800) 414-0168 (office) / 617-973-0983 (fax) http://www.mass.gov/reg/boards/ph

APPLICATION FOR A NEW STORE

MTT ROMNEY

KERRY HEALEY LIEUTENANT GOVERNOR

TIMOTHY R. MURPHY SECRETARY

PAUL J. COTE, JR. COMMISSIONER

RACE WOOKAS

APR 25 2006

BOARD OF PHARMACY

I hereby apply for a permit to operate a store for the transaction of retail drug business in accordance with the provisions of Chapter 112, General Laws.

\$351.00 licensure / application fee. Make check or money order for \$351.00 payable to the Commonwealth of Massachusetts. This fee is non-refundable.

- 1. Legal Name of Business. Ameridose, LLC
- 2. Full Business Address (Street Address, City, State and Zip). 50 Fountain Street, Framingham, MA 01702
- 3. Area Code and Telephone Number. 508-656-2653
- 4. All trade or business names ("D.B.A." names) used by same Corporation or by License. Ameridose, LLC
- 5. Type of ownership or operation (i.e., sole proprietorship, partnership, corporation). Limited Liability Company (LLC)

If corporation, please submit articles of corporation. Please see Attachment "A"

5. Names(s) and Social Security Number(s) of the owner(s) and/or operator(s) of the licensee. Please indicate type of ownership - Partnerships: the name of each partner and name address of partnership;

Corporations: the name and title of each corporate officer and director, the corporate names, name and address of parent company, if any, and the State of incorporation; Sole Proprietorship: the name of the sole proprietor and the address of the business entity. Please see Attachment "B"

- 7. Name of registered pharmacist charged with the management of the pharmacy. Sophia Pasedis, RPh, PharmD.
- 8. Registration number of above manager. 20217
- 9. Name(s) and registration number(s) of staff pharmacist(s) employed at pharmacy. Sophia Pasedis, RPh, PharmD.
- 10. Have any of the applicant(s) and/or managers-in-charge had: 1) any convictions related to the distribution of drugs (including samples); 2) any felony convictions; 3) any suspension(s) or revocation(s) or other sanction(s) by federal, state or local governmental agency of any license or registration currently or previously held by the applicant or license for the manufacture, distribution, or dispensing of any drugs, including controlled substances? NO

Have any applications for licensure been denied by any federal or state agency including any state board of pharmacy? NO

List and explain. Attach additional sheets if necessary. N/A

- 11. The applicant/licensee must notify the Board in writing of any changes in ownership or management within thirty (30) days of such change(s).
- 12. Social Security Number (Mandatory).

 Pursuant to M.G.L. c. 62C, s. 47A, the Division of Registration is required to obtain your social security number and forward it to the Department of Revenue. The Department of Revenue will use your social security number to ascertain whether you are in compliance with the tax laws of the Commonwealth.

List any licenses/certifications you hold in the United States or any country or foreign jurisdiction and the state/jurisdiction from which the license/certification was originally issued. Please attach a certificate of standing from each state or jurisdiction in which you are licensed/certified, indicating the status of your license and any relevant disciplinary information. Massachusetts Registered Pharmacist License #20217, Attachment "C."

- 14. Has any disciplinary action been taken against you by a licensing/certification board located in the United States or any country or foreign jurisdiction? Yes: □ No: X
 If yes, please state the details (use a separate sheet if necessary). N/A
- 15. Are you the subject of pending disciplinary actions by a licensing/certification board located in the United States or any country or foreign jurisdiction? Yes: ☐ No: X

 If yes, please state the details (use a separate sheet if necessary). N/A
- 16. Have you ever voluntarily surrendered or resigned a professional license to a licensing/certification board in the United States or any country or foreign jurisdiction? Yes: ☐ No: X
 If yes, please state the details (use a separate sheet if necessary). N/A
- 17. Have you ever applied for and been denied a professional license in the United States or any country or foreign jurisdiction? Yes; □ No: X

 If yes, please state the details (use a separate sheet if necessary). N/A

18. Pursuant to Board Regulations at 247CMR δ 6.01(3), The Board shall not register nor permit ownership of a pharmacy or pharmacy department by a practitioner with prescriptive privileges. By signing this application the applicant certifies that none of the owners, directors or officers have prescriptive privileges.

Affidavit (must be completed and notarized)

Pursuant to M.G.L. c. 62C, s. 49A, I certify under the penalties of perjury that I, to the best of my knowledge and belief, have filed all state tax returns and paid all state taxes required under law.

The applicant certifies that each person employed in any prescription drug distribution activity has the education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety, and security will at all times be maintained as required by law.

I hereby state that I am the person authorized to sign this application for all licensure; that all statements are true and correct in all respects and are made under the penalties of perjury.

Signature of pharmacist who is to manage the pharmacy or pharmacy department

April 5, 2006
Date

Social Security Number of the Manager of Record

Swom and subscribed before me this_	14th	_day of _ 👸	oril 2006
My commission expires $13/31/$	2010. Care	ie Joe Notary Pul	X leever
To be completed by the Board: Check	k\$_3 Date.	5/2/06	Number 6170

Received

APR 25 2006

BOARD OF PHARMACY

Application for Registration to Manage and Operate a New Community Pharmacy

Ameridose, LLC 50 Fountain Street Framingham, MA 01702 508-656-2653 fax 508-872-0044



MITT ROMNEY GOVERNOR

KERRY HEALEY LIEUTENANT GOVERNOR

TIMOTHY R. MURPHY SECRETARY

PAUL J. COTE, JR. COMMISSIONER

JEAN K. PONTIKAS DIRECTOR

The Commonwealth of Massachusetts Executive Office of Health and Human Services Department of Public Health Division of Health Professions Licensure

Board of Registration in Pharmacy 239 Causeway Street, Suite 200, 2nd Floor Boston, MA 02114 (800) 414-0168 (office) / 617-973-0983 (fax) http://www.mass.gov/reg/boards/ph

APPLICATION FOR REGISTRATION TO MANAGE AND OPERATE A NEW COMMUNITY PHARMACY

- (1) In order to be registered by the Board to manage and operate a pharmacy or pharmacy department and be issued a permit to do so, the registered pharmacist who shall be responsible for the management and operation of the pharmacy or pharmacy department shall obtain and submit to the Board an application for registration to manage and operate a pharmacy or pharmacy department available from the Board. A completed application shall be:
 - (a) fully and properly completed and signed, under the penalties of perjury, by the pharmacist who is to manage and operate the pharmacy or pharmacy department;
 - (b) accompanied by a statement of the scheduled hours during which the pharmacy or pharmacy department is to remain open, including the time of opening and closing during regular business hours for each day of the week; Attachment "D"
 - (c) accompanied by an application, available from the Board, for a Massachusetts controlled substance registration;
 - (d) accompanied by an application, available from the Board, for a certificate of fitness, if applicable;
 - (e) accompanied by a check or money order made payable, in the proper amount, to the "Commonwealth of Massachusetts Board of Registration in Pharmacy"; and
 - (f) accompanied by any additional information as determined by the Board.
 - (g) accompanied by an official blueprint or certified architectural plans drawn to scale clearly designating both the prescription and patient consultation areas (pharmacy department shall be outlined in RED).
- (2) A completed application to operate a pharmacy shall include:
 - (a) a copy of the corporation's Articles of Organization, signed and sealed by the Secretary of State if the corporation is incorporated in the Commonwealth;

(b) a copy of the corporation's Foreign Corporation Certificate, signed and sealed by the Secretary of State pursuant to M.G.L. c. 181, § 4, if the corporation in incorporated in another state: (c) a statement of the name and address of each officer and director of the corporation and the position held; nla (d) the d/b/a name of the corporation; and (f) if the corporation is not publicly owned, the total amount and type of stock issued to each stockholder and the names and addresses of said stockholder(s). (3) The Board shall not register nor permit ownership of a pharmacy or pharmacy department by a practitioner with prescriptive privileges. (4) Before acting upon any application for registration to manage and operate a pharmacy or pharmacy department, the Board may require a hearing and, if requested to do so, the applicant shall personally appear before the Board to answer questions to enable the Board to determine that issuance of a permit would be in the best interests of the public health, welfare and safety as set forth in M.G.L. c. 112, § 39. (5) The Board may require an inspection of the pharmacy or pharmacy department before final approval of the application is granted. All proposed pharmacies and pharmacy departments shall comply with the following requirements: (a) No application for registration to manage and operate a pharmacy or pharmacy department shall be approved unless, upon inspection, the following is maintained on the pharmacy premises: 1. a current copy or electronic version of the Massachusetts List of Interchangeable Drugs (MLID), including the Orange Book, Additional List, Exception List, and the latest supplements thereto; 2. a current copy or electronic version (with quarterly updates) of a compendia appropriate to the practice setting approved by the pharmacist manager of record. 3. a current copy or electronic version of Board Regulations 247 CMR 1.00 et seq.: 4. a balance capable of accurately weighing quantities as small as 13 milligrams, which balance shall be tested and sealed by the state or local sealer of weights and measures annually: 5. the equipment necessary to conduct the practice of pharmacy according to the standards set forth by most current edition of the United States Pharmacopoeia; 6. prescription labels which bear the name and address of the proposed pharmacy;

7. appropriate sanitary appliances, including a suitable sink which shall be equipped for hot and cold running water and which shall be situated in or near the area in which

prescriptions are to be filled;

8, whenever applicable, at least one bound book for recording sales of controlled substances which may be sold over-the-counter without a prescription; and 9. whenever applicable, at least one book for recording sales of alcoholic beverages and signatures of the purchasers of these beverages. (b) There shall be within every pharmacy or pharmacy department a prescription area of not less than 300 square feet to accommodate the appropriate pharmaceutical equipment, apparatus, and supplies, and to facilitate the proper preparation and compounding of prescribed medications. This area shall provide for an arrangement and storage of drugs that is calculated to prevent their accidental misuse. (c) Any pharmacy or pharmacy department which establishes a central intravenous admixture service (CIVAS) shall, in addition to the 300 square feet required by 247 CMR 6.01(6)(b), provide for a separate room referred to as a "clean room" apart from all other areas of the pharmacy or pharmacy department. This clean room shall meet the following requirements: 1. There shall be a minimum working area of 72 square feet; 2. it shall be closed on all sides except for a door and an opening to allow for the passage of materials; 3. it shall have a laminar flow hood with either vertical or horizontal air flow; 4. the laminar flow hood standards of operation of HEPA (High Energy Particulate Air) filters and prefilters must be determined and certification shall be made annually by a Board-approved hood certification service; 5. the Board shall be notified before beginning operation of the clean room to verify hood certification; 6. the area of the clean room shall be under continual positive pressure unless the hood is self-venting; and 7. applications for construction of a pharmacy with a clean room received after September 30, 1996 shall show the clean room located directly adjacent to the prescription area/department. (d) Patient Consultation Area. 1. A pharmacy must provide a designated consultation area, with signage stating "Patient Consultation Area", designed to provide adequate privacy for confidential visual and auditory patient counseling. The private consultation area must be accessible by a patient from the outside of the prescription dispensing area without having to traverse a stockroom or the prescription dispensing area. 2. 247 CMR 6.01(5)(d) shall be effective for all new or relocating pharmacies on April 1,

2005. All existing pharmacies must comply with 247 CMR 6.01(5)(d) by January 1,

2007.

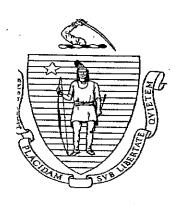
- (6) The Board shall issue a permit indicating the pharmacy or pharmacy department's registration number if the Board finds, in its reasonable discretion, that approving the application would be consistent with the best interest of public health, welfare and safety.
- (7) All fees submitted to the Board in connection with an application for registration to operate a pharmacy or pharmacy department, which are reviewed and acted upon by the Board, are nonrefundable.

Please be advised that no pharmacy and pharmacy department shall begin to operate until the application has been approved by the Board and: 1) the pharmacist Manager of Record has received from the Board a permit number to manage and operate the pharmacy and or pharmacy department, and 2) has received a controlled substances registration number.

For complete information regarding relocation regulations, please refer to 247 CMR 6.01 & 6.02. If additional information is necessary, please contact the Board office at (800) 414-0168.

To obtain a DEA number, please contact the Drug Enforcement Administration (DEA) office for an application. The address is: J.F.K. Federal Building

Drug Enforcement Administration Room E400 15 New Sudbury Court Boston, MA 02203-0131 (617) 557-2200



The Commonwealth of Massachusetts **Executive Office of Health and Human Service** Department of Public Health Division of Health Professions Licensure

Board of Registration in Pharmacy 239 Causeway Street, Suite 200, 2nd Floor Boston, MA 02114 (800) 414-0168 (office) / 617-973-0983 (fax) http://www.mass.gov/reg/boards/ph

APPLICATION FOR A NEW STORE

KERRY HEALEY LIEUTENANT GOVERNOR

TIMOTHY R. MURPHY SECRETARY

PAUL J. COTE, JR. COMMISSIONER

HACCHARDKAS

APR 25 2006

BOARD OF **PHARMACY**

I hereby apply for a permit to operate a store for the transaction of retail drug business in accordance with the provisions of Chapter 112, General Laws.

\$351.00 licensure / application fee. Make check or money order for \$351.00 payable to the Commonwealth of Massachusetts. This fee is non-refundable.

- 1. Legal Name of Business. Ameridose, LLC
- Full Business Address (Street Address, City, State and Zip). 50 Fountain Street, Framingham, MA 01702
- Area Code and Telephone Number. 508-656-2653
- All trade or business names ("D.B.A." names) used by same Corporation or by License. Ameridose, LLC
- Type of ownership or operation (i.e., sole proprietorship, partnership, corporation). Limited Liability Company (LLC)
 - If corporation, please submit articles of corporation. Please see Attachment "A"
- 5. Names(s) and Social Security Number(s) of the owner(s) and/or operator(s) of the licensee. Please indicate type of ownership - Partnerships: the name of each partner and name address of partnership;

Corporations: the name and title of each corporate officer and director, the corporate names, name and address of parent company, if any, and the State of incorporation; Sole Proprietorship: the name of the sole proprietor and the address of the business entity. Please see Attachment "B"

- 7. Name of registered pharmacist charged with the management of the pharmacy. Sophia Pasedis, RPh, PharmD.
- 8. Registration number of above manager. 20217
- 9. Name(s) and registration number(s) of staff pharmacist(s) employed at pharmacy. Sophia Pasedis, RPh, PharmD.
- 10. Have any of the applicant(s) and/or managers-in-charge had: 1) any convictions related to the distribution of drugs (including samples); 2) any felony convictions; 3) any suspension(s) or revocation(s) or other sanction(s) by federal, state or local governmental agency of any license or registration currently or previously held by the applicant or license for the manufacture, distribution, or dispensing of any drugs, including controlled substances? NO

Have any applications for licensure been denied by any federal or state agency including any state board of pharmacy? NO

List and explain. Attach additional sheets if necessary. N/A

- 11. The applicant/licensee must notify the Board in writing of any changes in ownership or management within thirty (30) days of such change(s).
- 12. Social Security Number (Mandatory).

 Pursuant to M.G.L. c. 62C, s. 47A, the Division of Registration is required to obtain your social security number and forward it to the Department of Revenue. The Department of Revenue will use your social security number to ascertain whether you are in compliance with the tax laws of the Commonwealth.

List any licenses/certifications you hold in the United States or any country or foreign jurisdiction and the state/jurisdiction from which the license/certification was originally issued. Please attach a certificate of standing from each state or jurisdiction in which you are licensed/certified, indicating the status of your license and any relevant disciplinary information. Massachusetts Registered Pharmacist License #20217, Attachment "C."

- 14. Has any disciplinary action been taken against you by a licensing/certification board located in the United States or any country or foreign jurisdiction? Yes: ☐ No: X

 If yes, please state the details (use a separate sheet if necessary). N/A
- 15. Are you the subject of pending disciplinary actions by a licensing/certification board located in the United States or any country or foreign jurisdiction? Yes: □ No: X

 If yes, please state the details (use a separate sheet if necessary). N/A
- 16. Have you ever voluntarily surrendered or resigned a professional license to a licensing/certification board in the United States or any country or foreign jurisdiction? Yes: □ No: X If yes, please state the details (use a separate sheet if necessary). N/A
- 17. Have you ever applied for and been denied a professional license in the United States or any country or foreign jurisdiction? Yes: □ No: X

 If yes, please state the defails (use a separate sheet if necessary). N/A

18. Pursuant to Board Regulations at 247CMR δ 6.01(3), The Board shall not register nor permit ownership of a pharmacy or pharmacy department by a practitioner with prescriptive privileges. By signing this application the applicant certifies that none of the owners, directors or officers have prescriptive privileges.

Affidavit (must be completed and notarized)

Pursuant to M.G.L. c. 62C, s. 49A, I certify under the penalties of perjury that I, to the best of my knowledge and belief, have filed all state tax returns and paid all state taxes required under law.

The applicant certifies that each person employed in any prescription drug distribution activity has the education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety, and security will at all times be maintained as required by law.

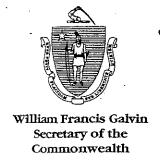
I hereby state that I am the person authorized to sign this application for all licensure; that all statements are true and correct in all respects and are made under the penalties of perjury.

Signature of pharmacist who is to manage the pharmacy or pharmacy department

April 5, 2006
Date

Social Security Number of the Manager of Record

Sworn and subscribed before me this_	14th	_day of _ 🔂	pril 2006
My commission expires $\frac{13}{31}$	a010. Cau	Notary Pu	Leeur
To be completed by the Board: Check	k\$ <u>3</u> 57 Date	4/2/06	Number 6170



The Commonwealth of Massachusetts

Secretary of the Commonwealth

State House, Boston, Massachusetts 02133

April 10, 2006

TO WHOM IT MAY CONCERN:

I hereby certify that a certificate of organization of a Limited Liability Company was filed in this office by

AMERIDOSE, LLC

in accordance with the provisions of Massachusetts General Laws Chapter 156C on February 8, 2006.

I further certify that said Limited Liability Company has filed all annual reports due and paid all fees with respect to such reports; that said Limited Liability Company has not filed a certificate of cancellation or withdrawal; and that, said Limited Liability Company is in good standing with this office.

I also certify that the names of all managers listed in the most recent filing are: GREGORY CONIGLIARO, BARRY J. CADDEN

I further certify, the names of all persons authorized to execute documents filed with this office and listed in the most recent filing are: GREGORY CONIGLIARO, BARRY J. CADDEN

The names of all persons authorized to act with respect to real property listed in the most recent filing are: GREGORY CONIGLIARO, BARRY J. CADDEN



In testimony of which,

I have hereunto affixed the

Great Seal of the Commonwealth

Villian Travino Galicin

on the date first above written.

Secretary of the Commonwealth

Processed By:MT

AMERIDOSE, LLC CERTIFICATE OF ORGANIZATION

FEB 0 8 2006

[47] [4]

SECRETARY SECRETARY OF THE SECRETARY OF

Pursuant to the provisions of the Massachusetts Limited Liability Company Act (the "Act") the undersigned hereby certifies as follows:

- 1. Name of the Limited Liability Company. The name of the limited liability company formed hereby (the "Company") is Ameridose, LLC.
- 2. Office of the Limited Liability Company. The address of the office of the Company in the Commonwealth required to be maintained by Section 5 of the Act is 50 Fountain Street, Framingham, MA 01702.
- 3. Agent for Services of Process. The name and address of the resident agent for services of process for the Company is Gregory Conigliaro, 50 Fountain Street, Framingham, MA 01702.
 - 4. <u>Date of Dissolution.</u> The Company is to have no specific date of dissolution.
 - 5. Manager. The Managers are:

Gregory Conigliaro 50 Fountain Street Framingham, MA 01702

Barry J. Cadden 50 Fountain Street Framingham, MA 01702

- 6. <u>Execution of Documents.</u> Either Manager is authorized to execute any documents to be filed with the Secretary of State of the Commonwealth of Massachusetts.
 - 7. <u>Business of the Company.</u>
 - (a) To provide unit dose repackaging services;
 - (b) To exercise all other powers necessary to or reasonably connected with the Company's business that may be legally exercised by limited liability companies under the Act; and
 - (c) To engage in all activities necessary, customary, convenient, or incident to any of the foregoing.
 - 8. Execution of Documents Relating to Real Property. Either Manager is authorized

to execute, acknowledge, deliver and record any recordable instrument on behalf of the Company purporting to affect any interest in real property, whether to be recorded with a registry of deeds or a district office of the Land Court.

IN WITNESS WHEREOF, the undersigned hereby affirms under the penalties of perjury that the facts stated herein are true, this 6 day of February, 2006.

Grego Congliano

Grego Congliano

Check/Voucher	#	89	
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The Commonwealth of Massachusetts Limited Liability Company (General Laws, Chapter 156C)

989316

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Filed this 8 day February, 2006

Aplen Francis Ballet

William Francis Galvin
Secretary of the Commonwealth

Name :	JONATHA,	ND	TAMKIN	*
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Phone	617	964	.2501	

Attachment "B"

Ameridose, LLC

50 Fountain Street, Framingham, MA 01702 Tel: 508-656-2653

Fax: 508.872-0044

TYPE OF OWNERSHIP

Limited Liability Company
Organized in the Commonwealth of Massachusetts

COMPANY OPERATORS/MANAGERS

1. Gregory A. Conigliaro, Manager



2. Barry J. Cadden, R. Ph., Manager



LLC OWNERS

1. Carla R. Conigliaro

Ownership: 55% membership interest



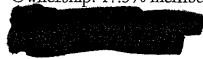
2. Barry J. Cadden, R. Ph.

Ownership: 17.5% membership interest



3. Lisa M. Conigliaro Cadden, R. Ph.

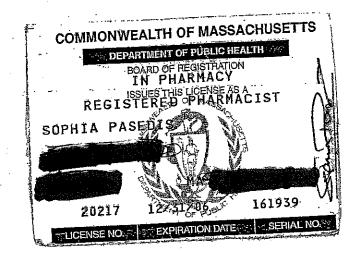
Ownership: 17.5% membership interest



4. Gregory A. Conigliaro

Ownership: 10% membership interest

Attachment "C"



DPH CONTROL# 0259680

IMPORTANT

If this license becomes lost or destroyed, notify your Board at the: Department of Public Health, 239 Causeway St., 5th Floor, Boston, MA 02114

Fyour name or address change, notify your Board to insure the proper mailing of your next Renewal Application. Always the proper making or your next renewal application. Always the first to your license number when corresponding with your soard. This license is subject to the provisions of the General Laws as amended. It is a privilege, and cannot be legal of a second or assigned to any other action. loaned or assigned to any other entity. Keep this license on your person, posted, or as required by law.

Please visit our web site at http://mass.gov/dph/boards



The Commonwealth of Massachusetts

Attachment

"D"

Executive Office of Health and Human Services
Department of Public Health

Division of Health Professions Licensure

MITT ROMNEY GOVERNOR

KERRY HEALEY LIEUTENANT GOVERNOR

TIMOTHY R. MURPHY SECRETARY

PAUL J. COTE, JR. COMMISSIONER

JEAN K. PONTIKAS DIRECTOR Board of Registration in Pharmacy 239 Causeway Street, Suite 200, 2nd Floor Boston, MA 02114 (800) 414-0168 (office) / 617-973-0983 (fax)

http://www.mass.gov/reg/boards/ph

PHARMACY HOURS

Name of Store: Ameridose, LLC

Street: 50 Fountain Street

City or Town: Framingham Zip Code: 01702

Phone Number: <u>508-656-2653</u>

	Open	Close	Hours
Monday	8:30 am	5:30 pm	9
Tuesday	8:30 am	5:30 pm	9
Wednesday	8:30 am	5:30 pm .	9
Thursday	8:30 am	5:30 pm	9
Friday	8:30 am	5:30 pm	9
Saturday	Closed	Closed	0
Sunday	Closed	Closed	0

Total Hours Per Week:

<u>April 14, 2006</u>

Date

Signature of Manager of Record or Duly Authorized Representative

Sophia Pasedis, RPh, PharmD.

Print Full Name

Application for Certificate of Fitness

Received

APR 25 2006

BOARD OF

Ameridose, LLC 50 Fountain Street Framingham, MA 01702 508-656-2653 fax 508-872-0044



MITT ROMNEY GOVERNOR

KERRY HEALEY
LIEUTENANT GOVERNOR

TIMOTHY R. MURPHY SECRETARY

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http://www.mass.gov/reg/boards/ph

APR 25 Z000

Received

BOARD OF PHARMACY

APPLICATION FOR A CERTIFICATE OF FITNESS Manager of Record Must Complete Application. Fee: \$120.00

I, Sophia Pasedis (name), at 508-656-2653 (telephone), of 50 Fountain Street (street address), Framingham (city), MA (state), 01702 (zip code), a registered pharmacist, certificate number 20217 being now. actively engaged in conducting a retail drug business as sole owner or Manager of Record for the firm / corporation of Ameridose, LLC do hereby apply for CERTIFICATE OF FITNESS, claiming to be a proper person to be entrusted with the authority to:

- 1) Use alcohol for the manufacture of United States Pharmacopeia and National Formulary preparations and all medicinal preparations unfit for beverage purposes,
- 2) Sell, in accordance with the laws of the Commonwealth, alcohol and alcoholic liquors, and that the public good will be promoted by the granting of such license.

I have <u>\$0</u> (give dollar amount) invested in said retail business and will comply with the laws of this Commonwealth and the regulations of the Board relating to the use and sale of the alcohol and alcoholic liquors.

I certify that I have not been convicted of a violation of said laws within one year prior to the date of this application.

I agree to notify the board at once if I cease to conduct the retail drug business at the above location and will return the certificate issued thereon.

Signed Casea Date: April 14, 2006

Please submit non-refundable check or money order for \$120.00 payable to the Commonwealth of Massachusetts.

	- Please do not write below this line -	
Check/	M.O. Date <u>\$/2/0</u> 6	

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH BOARD OF REGISTRATION IN PHARMACY

COMPOUNDING PHARMACY INSPECTION REPORT

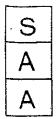
	Assignment number:	1/13/06
New Pharmacy: 🔽	Compliance:	Relocation:
ADMINISTRATIVE 1) Corporation Name: America Dos 2) DBA Name: America dase 3) Address: 50 tour train 4) City / Town: Tarmina fram 5) Telephone #: 508 - 553 - 2553 6) Registrant: Sophic Ascelic. 7) DEA #	Exp. Date:	202 T
8) Board of Pharmacy Control Substant 9) Pharmacy Hours of Operation: M-F		xp. Date:
REFERENCES SOURCES 1) Rules and Regulations Board of Pharmacy 247 CM 2) FDA Guidelines 795 (non sterile) 797 (sterile) 3) USP Guidelines 4) Facts and Comparisons (latest edition) Updates inserted CD Rom versions: Y N Updated qua 5) USP / DI Volume 1 Volume 2 6) American Hospital Formulary Service Drug Informa 7) American Medical Association Drug Evaluations 8) Gold Standard Y N Updated qua 9) Mosby's Drug Consult 10) M.L.I.D. (latest version)	480 N N N N arterly N N N N N N N N N N N N N N N N N N N	
EQUIPMENT 1) Sufficient Equipment 2) Balance information: Torsion balance / scale and Electronic balance Scale with print out: Y 1) Number of Sinks in pharmacy location:	weights Seal Date: Seal Date: N Seal Date:	<u>. </u>
4) Hot and Cold running water 5) Computer Software Name PL Software 5) Label Compliance Legend label compliant with interchange 7) Written copy of Policy & Procedures Manual on locathe handling of Medication Errors	(Y) N	

O.B.R.A					
1) Counseling Sign (11" x 14") posted:	$(\mathbf{Y})^{N}$				
2) Designated Confidential Counseling Area	N (S)		•		
3) Drive Up Window: Y N Sign Pos		> .	•	•	
		, Hisiaa ma	sL		
		tified Te	cn		
Then y studenty	Grad. Pharmacist?	٠.			
5) Record maintained of Offer to Counsel	SY N	·		· -	
6) Monographs used? All prescriptions	New prescr	iptions o	nly 🔪 🔒		
7) Prospective DUR on new prescriptions?	(Y) N	6	y end	. user	
Conducted by: Pharmacists? Certified		. Tech?		·	
Intern / Student /Grad. P	harmacist				
E.D.T.					
1) Random Sampling of Purported Prescriptions: DEA # (Correct	Y.	N		
2) Identifier of Recipient on Rx.	Ϋ́N	•.	,,	<i>)</i>	
3) Transmitting by Computer on time?	Y N		•		
4) Counseling or Intervention Book	Ϋ́N			TIPUTE	L
5) Patient Drug Regimen Review completed prior to dispe	noiteation	Υ	· 14		
-y	rising medication.	,	N		
RECORD KEEPING				•	
1) Biennial Inventory Readily Retrievable	ΥN				,
Date of last inventory:	1 14	\		wed Stone	
2) Date of Last Change of Manager	NIA .	. /	Perio	evet	
3) 222 Forms Sampling Compliant	NA			~ ~	
4) Power of Attorney on File	ΥN		1.1	Shinz	
Located where:	Y N	- \ -	New		
		1			
5) Perpetual Inventory Schedule II	ΥN	- 1			
Date Last Reconciled:		- /	-	•	•
Date of Inspection:	_	<i>.</i> /.			
6) Schedule III through Schedule IV controlled substances		the phại	macy?		
7) 0 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Y NA		• •	1	
7) Controlled substances in Schedule II locked and stored	in the pharmacy	Υ	N	- {	
B) Controlled substance deliveries are delivered directly to	the pharmacy dept	Υ.	N	l l	
9) Biennial Inventory readily retrievable?	ΥN		*	1 revise	عليرك
Last Inventory date;				(,-0	
10) Inventory taken for Change of pharmacy manager	ΥN			٠	
Date taken Name of I	incoming pharmacis	t		1	
Name of C	Dutgoing pharmacis			<u> </u>	•
 Procedures in practice to validate controlled substance 	prescription	Υ	N	1	
12) Computerized records of distribution by schedule	ΥN			1	
 a) Signed daily by pharmacist 	YN			1	
b) Central Record Keeping Authority	ΥN		•		
L3) Schedule II prescriptions are segregated	ΥN		•	- 1	
(4) Schedule III, IV, and V prescriptions maintained in a se	parate file	Υ	N	1.	•
(5) Schedule VI prescriptions and syringes and instruments	s filed together	Ÿ	· N		
,	moa cogcarci	•	^{۱۹}	- .	
CODE OF PROFESSIONAL CONDUCT – 247 CMR 9.01	•				
) Patient Confidentiality	Y N	-	•		
2) Corresponding Responsibility: making sure prescription is	r for a locitimate				
use in usual course of practice,	7 7				
Doctor Shoppers as it relates to OBRA	N N		•		
A normal pulphhelp ap if Leiging ID ODKY	(YY) N				

4) Faxing of Prescriptions
a) plain paper fax
b) location of fax: Secure 10 Cution
c) accept Schedule II fax prescriptions for reference? Y Nr
5) Prescribers signature is on face of prescription faxed N
6) Faxed prescription or drug order is marked
Electronically Transmitted RX Y (NA)
7) Fay includes the identification number of the conding formula.
V) Decord maintained for the action of the second of the s
Computerized record: YN Hard copy log Y
(1) Empresonar puthorized prescriptions in (1) 1 7 1 1 1 1 1 1 1 1
mN Manufacat Cathanathanathanathanathanathanathanatha
i.e. faves: marked with both: Flortranically transmitted by and total
i.e. faxes: marked with both: Electronically transmitted RX and Authorization for Emergency Dispensing
b) Written prescription is postmarked with in 7 days to pharmacy Y N
c) Non-compliant physicians reported to DPH and DEA? Y N 10) Copies of pharmacists license posted Y N
Continued to the continue of t
Copies of technicians licenses posted N N N
11) Names badges and titles noted
12) Manager of record is responsible for(setting forth) policy & procedures N
a) staff is adequately trained
b) technician manual on premises N N
c) ratio pharmacists to technicians 3:4
13) Number of Students/ Interns Reg. Pharm. techs Cert. Pharm. techs Pharmacists
14) After hours access to pharmacy?
15) Evidence of security cameras Y N
(6) Quarantine area for control substances in schedule II. III. IV. V recalls or expired product
6) Quarantine area for control substances in schedule II, III, IV, V recalls or expired product
6) Quarantine area for control substances in schedule II, III, IV, V recalls or expired product segregated from current inventory
6) Quarantine area for control substances in schedule II, III, IV, V recalls or expired product segregated from current inventory N 7) Quarantine area for schedule VI expired or recalled items Y N
6) Quarantine area for control substances in schedule II, III, IV V recalls or expired product segregated from current inventory 7) Quarantine area for schedule VI expired or recalled items 8) Biohazard waste appropriately flagged Y N
6) Quarantine area for control substances in schedule II, III, IV V recalls or expired product segregated from current inventory N Output O
6) Quarantine area for control substances in schedule II, III, IV, V recalls or expired product segregated from current inventory 7) Quarantine area for schedule VI expired or recalled items 8) Biohazard waste appropriately flagged 9) Name of Reverse Distributor 4 telephone number 6) ICALLO 1011
6) Quarantine area for control substances in schedule II, III, IV V recalls or expired product segregated from current inventory N N N N N S) Biohazard waste appropriately flagged Y N N 9) Name of Reverse Distributor date of last return: O) JCAHO approved?
6) Quarantine area for control substances in schedule II, III, IV V recalls or expired product segregated from current inventory N N Ouarantine area for schedule VI expired or recalled items Y N S) Biohazard waste appropriately flagged Y N 9) Name of Reverse Distributor telephone number date of last return: O) JCAHO approved? Y N 1) Log noting re-packaging date, expiration date, lot number, manufacturer, expiration date
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16) Quarantine area for control substances in schedule II, III, IV V recalls or expired product segregated from current inventory No. 17) Quarantine area for schedule VI expired or recalled items of No. 18) Biohazard waste appropriately flagged of No. 19) Name of Reverse Distributor of No. 19) Name of Reverse Distributor of No. 19) Name of Reverse Distributor of No. 19) Icah of Italian
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16) Quarantine area for control substances in schedule II, III, IV V recalls or expired product segregated from current inventory No. 17) Quarantine area for schedule VI expired or recalled items of No. 18) Biohazard waste appropriately flagged of No. 19) Name of Reverse Distributor of Lelephone number of No. 19 Lelephone number of N
16) Quarantine area for control substances in schedule II, III, IV V recalls or expired product segregated from current inventory No. 27) Quarantine area for schedule VI expired or recalled items of the No. 8. Biohazard waste appropriately flagged of the No. 9. Name of Reverse Distributor of the Lephone number of the Lephone nu
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Information:	ture Service) /	Compoundir	ig	
•				•
1) Clean room minimum of 72 sq. ft		N	•	
2) Clean room adjacent to prescription department		N		
3) Room under continual positive pressure	\sim	N		
4) LIVAS letter from Board posted	\sim	N		
date of letter			٠	
5) Adequate Reference Standards	Y·	N		
6) Sterile Products:				
Laminar Flow Hood (name)	Expiration date	<u> </u>	· 1	
Vertical Flow Hood (name)	Expiration date	Enc	isse a	٠,
Serviced by:	Telephone #			: .
7) Written Quality Assurance Guidelines to include ase	ptic techni que, s te	erility, stability	and	
Endotoxin testing?	Y	N		
8) Pharmacy will test and sterilize vials and stoppers for	or sterile products	?	•	
9) Adequate Education in Sterile Products Last update		-service	-	
10) Batch log is initialed or signed by technician prepare	ring the compound	d? Y	N	
11) Quality controls in place	\sim	N		
12) Log for such controls in place?	\mathcal{C}	N		•
a) Air Quality	(¥)	N		
b) Filters	$\langle \gamma \rangle$	N		
c) Floors and Equipment cleaned		N		
d) IV room and Ante Room clean	$\langle \gamma \rangle$	N		
13) Computer Software Name TK	Support Numbe	er.		
Label Compliance: Compounding label:	(2)	N		
IV label	$\widetilde{\mathfrak{D}}$	N	•	
14) All prescriptions are patient specific		N		•
15) Compounding practices are in conformance with U.	.S. FDA guidelines		N	
16) All bulk compounding materials will be purchased f			••	
approved manufacturer	Y	N		
17) Certificates of analysis will remain filed on site and	be readily retrieva			
	Υ	N ·		
18) Policy exists for how beyond use dates will be dete	ermined? Y	N		
19) Batch log sheets will be kept on all compounded pr	escriptions compo		de product	
name, expiration dates, manufacturers lot numbers,	pharmacy lot num	nbers, name of	natient /	ry number
who calculated, who compounded, who verified the	prescription?	Y) N	padent /	1X Humber
20) Pharmacy will advertise the business as a compoun	ider and not the si		e?	
, , , , , , , , , , , , , , , , , , , ,	(Y)	N	5:	
SUPPLIER INFORMATION				•
1/		•		
1) HB Pena 2) Mc Ka	SS00 31			
	<u> </u>		. •	
PHARMACIST ROSTER (List or see attach Roster)		•		
1)			•	
2)				
3)	,,,, <u>,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,</u>			
4)		· · · · · · · · · · · · · · · · · · ·	-	
· /				

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Scientific Air Analysis, Inc. 47 Fatima Drive

47 Fatima Drive
Ashland, MA 01721
(508) 881-7100
(508) 881-7105 FAX
1-800-287-5252 MA ONLY

+5 FM

		1000
	CLIENT: AMERIDOSE	TEST#: (0808
	ADDRESS:	m#:, 8
	CITY, STATE:	MODEL#: S6603A
	CONTACT:	SERIAL#: 88020
	TEL#:	LOCATION: CLARROOM
	TEST DATE: 7-6-06	NEW/USED: New
	RECALL DATE: 7-31-07	PASS/FAIL: PASSES
	SUPPLY AIRFLOWS	EXHAUST AIRFLOWS
	SUPPLY RANGE: NA FPM	EXHAUST RANGE: 253-280 FPM
		DUCTED:
)	SR: 54 52 50 49 47 53 58 56 52	R1: 270 276 273 EXH OP: (76 FT2 R2: 275 273 ACC OP: 789 FT3
Ü	SC: 53 54 58 5251 545453 54	R3: 271 271 273
7	SF: 57 23 28 2022 21 282 23	R4: 268 224 267 EXH CFM: 397
	L: 49 H: 58 AVG FPM:	EL:267 EH:276 EXHAVG FPM: 272
	AIRFLOW GAUGE: • 275	FACE VELOCITY: 107
	UV.BULB INT: MA- UW/CM2	MOTOR SPEED: 45 %
	TEST R	
	DOWNFLOW VELOCITY PASSED, AVG FRANGE OF: FPM. ALL INDIVIDU	PM OF : 52,54,53 IS WITHIN ACCEPTANCE AL READINGS ARE WITHIN 20% OF DOWNFLOW
	AVERAGE.	AL KLADINGS AKL: WITHIN 2076 OF DOWNFLOW
	FACE VELOCITY PASSED, AVG FPM OF	: /07 IS WITHIN ACCEPTANCE
	RANGES OF: (00 -10 FPM. AIRFLOW SMOKE PATTERNS PASSED, NO	SMOKE ESCAPED FROM THE CABINET, THERE
	ARE NO DEAD SPOTS OR REFLUX OVER THE	E WORK SURFACE.
٠		ON DOES NOT EXCEED 0.01 % AT ANY POINT. NITATION FOUNDATION #49-2002
		ABRATED NIST # ID #_USED
	ALNOR 8570, 99057017 10-0	
		6-05 822/249620 A2; 4-05 822/264157 (A3)
	ALNOR 550, 2664 10-0 ATI TDA-2G, 11119 10-0	
	UVC-254, C.83961 12-1	
	COMMENTS:	
	[] NO ADJUSTMENTS REQUIRED AT THIS TO ADJUSTED / XEROED APAGNEHELIC GAU	
	UB BULB INTENSITY GOOD / FAIR / POO	
	[] INCREASED / DECREASED MOTOR BLOV	WER SPEED TO REBALANCE AIRFLOW.
	CERTIFIER: APTISTED EXHA	est DANGER TO BALANCE AIRPLOY
	Ct 11	•

Scientific Air Analysis, Inc. 47 Fatima Drive

47 Fatima Drive Ashland, MA 01721 (508) 881-7100 (508) 881-7105 FAX 1-800-287-5252 MA ONLY

	CLIENT: AMERIDOSE	TEST#: 10775
	ADDRESS:	ID#: # 7
	CITY, STATE:	MODEL#: SG 603A
	CONTACT:	SERIAL #1. 58004
	TEL#:	LOCATION: CLA RM.
·	TEST DATE: 7-6-06	NEW/USED: New
•	RECALL DATE: 7-31-07	PASS/FAIL: PASC
	SUPPLY AIRFLOWS	EXHAUST AIRFLOWS
• .	SUPPLY RANGE: MA FPM	EXHAUST RANGE 253 - 250 FPM DUCTED;
50-60	- -	R1: 246 253 258 EXH OP / 46 FT2
50-60	SC: 53 50,475653 58458 54	R2: 268: 277 24/ ACC OP3. F9FT2 R3 263 282 26 EXH CEM: 5 CO
47-57	SF:4753514956505351 51	280 291 272 388
	L: 47 H: 62 AVG FPM: 54	EL 241 EH: 291 EXH AVG FPM: 266
	AIRFLOW GAUGE: 275	FACE VELOCITY: 105
	UV BULB INT : UW/CM2	MOTOR SPEED: 31 %
	AVERAGE. FACE VELOCITY PASSED, AVG FPM OF RANGES OF: /60 - // 0 FPM. AIRFLOW SMOKE PATTERNS PASSED, NO ARE NO DEAD SPOTS OR REFLUX OVER THE FILTER LEAK TEST PASSED, PENETRATE REFERENCE STANDARD NATIONAL SA	PM OR 56,54,57 IS WITHIN ACCEPTANCE AL READINGS ARE WITHIN 20% OF DOWNFLOW IS WITHIN ACCEPTANCE SMOKE ESCAPED FROM THE CABINET, THERE
	ALNOR 8570, 99057017 10-04	4-05 822/264157 A1: 6-05 822/249620 A2: 4-05 822/264157 A3: 4-05 822/264157 A4:
	COMMENTS: NO ADJUSTMENTS REQUIRED AT THIS TO ADJUSTED ZEROED MAGNEHELIC GAU [] UB BULB INTENSITY GOOD / FAIR / POOD [] INCREASED / DECREASED MOTOR BLOW CERTIFIER:	GE. ALARM OPERATING PROPERLY. R. EXHAUST OPERATING PROPERLY.

Scientific Air Analysis, Inc.

47 Fatima Drive Ashland, MA 01721 (508) 881-7100 (508) 881-7105 FAX 1-800-287-5252 MA ONLY

•	CLIENT: AMERIDOSE	TEST#: 10756			
,	ADDRESS:	ID#: #6			
•	CITY, STATE:	MODEL#: SG 603A			
•	CONTACT:	SERIAL# 88018			
	TIT #.	LOCATION: CLA RM			
	TEST DATE: 7-6-06	NEW/USED: New			
1	TEST DATE: 7-6-06 RECALL DATE: 7-31-07	PASS/FAIL: PASS			
-	SUPPLY AIRFLOWS	EXHAUST AIRFLOWS			
	SUPPLY RANGE: NA FPM	EXHAUST RANGE: 253-280 FPM .T.			
		DUCTED:			
50-60	SR: 4854545656525958 55	R1: 254 250 266 EXHOP/46FT2 R2: 26 247 254			
50-60	SC:5258546254485455 55				
47-57	SF: 53 56 61 5T 53 5P 54 50 55	R4: 269 298 265 EXH CFM: 388			
ı	L: 48 H: 62 AVG FPM:55	EL247EH: 290EXHAVG FPM: 266			
	AIRFLOW GAUGE: 295	FACE VELOCITY: /65			
•	UV BULB INT: UW/CM2	MOTOR SPEED: %			
•	TEST R	ESULTS			
	DOWNFLOW VELOCITY PASSED, AVG F. RANGE OF: FPM. ALL INDIVIDUAL AVERAGE.	PM OE 55,55,55 IS WITHIN ACCEPTANCE AL READINGS ARE WITHIN 20% OF DOWNFLOW			
	FACE VELOCITY PASSED, AVG FPM OF	: (OS IS WITHIN ACCEPTANCE			
	RANGES OF: (OO - (10) FPM.	•			
CT CC TE TE RE SU SO-60 SC 47-57 SF L: All UV DC RA AV FA RA AII AII AII UV CC XX [] [] []	AIRFLOW SMOKE PATTERNS PASSED, NO SMOKE ESCAPED FROM THE CABINET, THERE ARE NO DEAD SPOTS OR REFLUX OVER THE WORK SURFACE.				
		ON DOES NOT EXCEED 0.01 % AT ANY POINT. NITATION FOUNDATION #49-2002			
		IBRATED NIST# ID# USED			
	ALNOR 8570, 99057017 10-0 ALNOR 8570, 99057020 6-0	4-05 822/264157 (1:) 6-05 822/249620 A2:			
	ALNOR 550, 2664 10-0	· · · · · · · · · · · · · · · · · · ·			
•	ATI TDA-2G, 11119 10-0				
	UVC-254, C.83961 12-1	5-05 UVI.2541335 UI:			
	COMMENTS:				
	NO ADJUSTMENTS REQUIRED AT THIS TO ADJUSTED (CEROED MAGNEHELIC GAU				
	UB BULB INTENSITY GOOD / FAIR / POO				
· <u>L</u>	[] INCREASED / DECREASED MOTOR BLOW	- · ·			
F	CERTIFIER:	· · ·			

Scientific Air Analysis, Inc.

47 Fatima Drive
Ashland, MA 01721
(508) 881-7100
(508) 881-7105 FAX
1-800-287-5252 MA ONLY

+5 LFX

BIOLOGICAL SAFETY CABINET SERVICE REPORT

10807 AMERIDOSC TEST#: CLIENT: ID#: ADDRESS: MODEL#: SG603A CITY, STATE: SERIAL#: 88012 CONTACT: LOCATION: CLARROOM TEL#: 7-6-06 NEW/USED: New TEST DATE: PASSED RECALL DATE: 7-31-07 PASS/FAIL: **EXHAUST AIRFLOWS** SUPPLY AIRFLOWS EXHAUST RANGE: 253-280 **FPM** SUPPLY RANGE: DUCTED: NO EXH OP: 1-46 FT2 R1: 270 221 225 SR: 3658615452565858 R2: 224 278 283 SC: 5453 5558 5258 5353 ACC OP: 3-87 FT2 R3: 269 229 273 EXH CFM: 402 SF: 4951 575251 595854 R4: 725 270 278 EL: 267 EH: 288 EXH AVG FPM: 275 L: 249 H: 59 AVG FPM: 108 .30 FACE VELOCITY: AIRFLOW GAUGE: MOTOR SPEED: 45 % UW/CM2 UV BULB INT: MA TEST RESULTS DOWNFLOW VELOCITY PASSED, AVG FPM OF: 57, 57, 57 IS WITHIN ACCEPTANCE FPM. ALL INDIVIDUAL READINGS ARE WITHIN 20% OF DOWNFLOW RANGE OF: AVERAGE. 108 IS WITHIN ACCEPTANCE PASSED, AVG FPM OF: FACE VELOCITY RANGES OF: 200 - 220 FPM. AIRFLOW SMOKE PATTERNS PASSED, NO SMOKE ESCAPED FROM THE CABINET, THERE ARE NO DEAD SPOTS OR REFLUX OVER THE WORK SURFACE. FILTER LEAK TEST PASSED, PENETRATION DOES NOT EXCEED 0.01 % AT ANY POINT. NATIONAL SANITATION FOUNDATION #49-2002 REFERENCE STANDARD NIST# ID# USED **CALIBRATED** TESTING INSTRUMENTS 822/264157 AD 10-04-05 ALNOR 8570, 99057017 822/249620 6-06-05 ALNOR 8570, 99057020 822/264157 A 10-04-05 ALNOR 550, 2664 10-04-05 ر A4) 822/264157 ATI TDA-2G, 11119 UVL2541335 U1: 12-15-05 UVC-254, C.83961 **COMMENTS:** [NO ADJUSTMENTS REQUIRED AT THIS TIME. [] HOOD FAILED. [4 ALARM OPERATING PROPERLY. ADJUSTED (ZEROED MAGNEHELIC GAUGE. EXHAUST OPERATING PROPERLY. UB BULB INTENSITY GOOD / FAIR / POOR. [] INCREASED / DECREASED MOTOR BLOWER SPEED TO REBALANCE AIRFLOW.

andle of Clean Rooms and Laminar Flow Follinment

Store Olane

CERTIFIER:

Scientific Air Analysis, Inc. 47 Fatima Drive

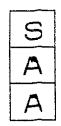
47 Fatima Drive Ashland, MA 01721 (508) 881-7100 (508) 881-7105 FAX 1-800-287-5252 MA ONLY ts FPM

	•	
	CLIENT: AMBRIDOSE	TEST #: 10806
	ADDRESS:	m#: +
	CITY, STATE:	MODEL#: SEGUSA
	CONTACT:	SERIAL#: \$8029
	TEL#:	LOCATION: CLEARROOM
	TEST DATE: 7-6-06	NEW/USED: New
	RECALL DATE: 7-21-07	PASS/FAIL: PASSEO
	SUPPLY AIRFLOWS	EXHAUST AIRFLOWS
•	SUPPLY RANGE: NY FPM	EXHAUST RANGE: 253-280 FPM
	- CONSIGNATION 49 53	R1: 264 273 271 EXH OP: 1.46 FT2
	3R - C 5 \ C 3 \ C 3 \ C 3 \ C 3 \ C 4 \ C	R2: 260 283 264 ACC OP: 3-89 FT2
	SC:23201129	R3: 258 213 271 EXH CFM: 391
	SF: 44 525355 57 5458 53 53	264 264 264 BAH CIM. 5 [
	L: 49 H: 58 AVG FPM: N/2	EL: 258 EH: 283 EXHAVG FPM: 268
	AIRFLOW GAUGE: . 36	FACE VELOCITY: 106
	UV BULB INT: WA UW/CM2	MOTOR SPEED: 45 %
	TEST R	ESULTS
		PM OF: 53,55,53 IS WITHIN ACCEPTANCE AL READINGS ARE WITHIN 20% OF DOWNFLOW
	AVERAGE. FACE VELOCITY PASSED, AVG FPM OF	: 106 IS WITHIN ACCEPTANCE
	RANGES OF: 100 ~ L(D FPM.	
	ARE NO DEAD SPOTS OR REFLUX OVER THE	SMOKE ESCAPED FROM THE CABINET, THERE E WORK SURFACE.
	FILTER LEAK TEST PASSED, PENETRATI	ON DOES NOT EXCEED 0.01 % AT ANY POINT.
		NITATION FOUNDATION #49-2002
	TESTING INSTRUMENTS CAL ALNOR 8570, 99057017 10-0	IBRATED NIST # ID # USED 4-05 822/264157 △ ◯
	ALNOR 8570, 99057020 6-0	6-05 822/249620 A2:
	ALNOR 550, 2664 10-0 ATI TDA-2G 11119 10-0	
	ATI TDA-2G, 11119 10-0 UVC-254, C.83961 12-1	
	COMMENTS:	
	14 NO ADJUSTMENTS REQUIRED AT THIS	TIME. [] HOOD FAILED. JGE. [ALARM OPERATING PROPERLY.
	[4] ADJUSTED ZEROED MAGNEHELIC GAU	
	[] INCREASED / DECREASED MOTOR BLOV	
	CERTIFIER:	
	Store O lan	

Scientific Air Analysis, Inc. 47 Fatima Drive

47 Fatima Drive Ashland, MA 01721 (508) 881-7100 (508) 881-7105 FAX 1-800-287-5252 MA ONLY

		مستدد مسير مهيورية
•	CLIENT: AMERI DOSE	TEST#: 10755
-	ADDRESS:	D#: #3
	CITY, STATE:	MODEL#: 56 603 A
	CONTACT:	SERIAL#: 88026
	TEL#:	LOCATION: CLH RM
•	TEST DATE: 7-6-06	NEW/USED: New
	RECALL DATE: 7-31-07	PASS/FAIL: PASS
•	SUPPLY AIRFLOWS	EXHAUST AIRFLOWS
	SUPPLY RANGE: A/A FPM	EXHAUST RANGE: 253-250 FPM NO
50-60	SR: 5349565855 615557 55	RI: 249 244 256 EXH OP: 1.46FT2
50-60	80:50 47545289 565457 54	- 23 9 46 237 ACCORD CARTO
47-57	SF:535648524956525853	R4: 21% 284 277 EXH CFM: 387
· Addition	L: 47 H: 61 AVG FPM: 54	EL 244EH: 286EXH AVG FPM: 265
,	AIRFLOW GAUGE: -36	FACE VELOCITY: 104
	UV BULB INT: N/A UW/CM2	MOTOR SPEED: 40 %
	TEST RI	ESULTS
	DOWNFLOW VELOCITY PASSED, AVG FOR RANGE OF: FPM. ALL INDIVIDUA	PM OF 55,54,53 IS WITHIN ACCEPTANCE AL RÉADINGS ARE WITHIN 20% OF DOWNFLOW
	AVERAGE	•
	FACE VELOCITY PASSED, AVG FPM OF RANGES OF: (OO -/10 FPM.	: 104 is within acceptance
	AIRFLOW SMOKE PATTERNS PASSED, NO	SMOKE ESCAPED FROM THE CABINET, THERE
,	ARE NO DEAD SPOTS OR REFLUX OVER THE	E WORK SURFACE. ON DOES NOT EXCEED 0,01 % AT ANY POINT.
		NITATION FOUNDATION #49-2002
	TESTING INSTRUMENTS CAL	IBRATED NIST# ID# USED
		4-05 822/264157 A1:
	ALNOR 8570, 99057020 6-0 ALNOR 550, 2664 10-04	6-05 822/249620 A2: 4-05 822/264157 A3;
	ATI TDA-2G, 11119 10-04	
	UVC-254, C.83961 12-15	
	COMMENTS:	
	NO ADJUSTMENTS REQUIRED AT THIS T ADJUSTED (ZEROED) MAGNEHELIC GAU	7.5
	[] UB BULB INTENSITY GOOD / FAIR / POOR	
\	[] INCREASED / DECREASED MOTOR BLOW	
j.	CERTIFIER:	
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Scientific Air Analysis, Inc.

+5 FPM

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BIOLOGICAL SAFETY CABINET SERVICE REPORT

10805 AMERIDOSE TEST#: CLIENT: \mathbf{Z} ID#: ADDRESS: 56603A MODEL#: CITY, STATE: 88019 SERIAL#: CONTACT: LOCATION: CLEARROOM TEL#: 7-6-06 NEW/USED: New TEST DATE: RECALL DATE: 7-31-07 PASS/FAIL: PASSEO **EXHAUST AIRFLOWS** SUPPLY AIRFLOWS EXHAUST RANGE: 253-280 FPM **FPM** SUPPLY RANGE: DUCTED: NO SR: 5452535357545052 RI: 264 275 273 EXH OP: 1.46 FT2 SC: 49 56 52 51 54 53 5257 R3: 267 278 275 ACC OP: 3.89 FT2 SF: 48 52 45 49 57 53 5455 R4: 269 270 263 EXH CFM: 397 L: 45 H: 59 AVG FPM: Ma EL: 257 EH: 278 EXH AVG FPM: 269 . 225 FACE VELOCITY: AIRFLOW GAUGE: MOTOR SPEED: 45 % UV BULB INT: N/A UW/CM2 TEST RESULTS DOWNFLOW VELOCITY PASSED, AVG FPM OF: 53,53,52 IS WITHIN ACCEPTANCE RANGE OF: FPM. ALL INDIVIDUAL READINGS ARE WITHIN 20% OF DOWNFLOW AVERAGE. PASSED, AVG FPM OF: 106 IS WITHIN ACCEPTANCE FACE VELOCITY RANGES OF: 100 - 110 FPM. AIRFLOW SMOKE PATTERNS PASSED, NO SMOKE ESCAPED FROM THE CABINET, THERE ARE NO DEAD SPOTS OR REFLUX OVER THE WORK SURFACE. FILTER LEAK TEST PASSED, PENETRATION DOES NOT EXCEED 0.01 % AT ANY POINT. NATIONAL SANITATION FOUNDATION #49-2002 REFERENCE STANDARD NIST# ID# USED **CALIBRATED** TESTING INSTRUMENTS 822/264157 AI 10-04-05 ALNOR 8570, 99057017 822/249620 A2: 6-06-05 ALNOR 8570, 99057020 822/264157 (A3 10-04-05 ALNOR-550, 2664 822/264157 (A4: 10-04-05 ATI TDA-2G, 11119 12-15-05 UVL2541335 U1: UVC-254, C.83961 COMMENTS: 19 NO ADJUSTMENTS REQUIRED AT THIS TIME. [] HOOD FAILED. [b] ADJUSTED ZEROED MAGNEHELIC GAUGE. [1] ALARM OPERATING PROPERLY. UB BULB INTENSITY GOOD / FAIR / POOR. [4 EXHAUST OPERATING PROPERLY.

Stac O'Nour

CERTIFIER:

1 | INCREASED / DECREASED MOTOR BLOWER SPEED TO REBALANCE AIRFLOW.

	NEFAU	VAGING	RECURD
Medication	Str	rength	_TRACKING#
Manufacturer	Manufacturer	's Lot#	Manufacturer's Exp Date:
Color/Form	ID Inscription		Customer
Date Received	Quantity Receiv	ved	Tech Signature
REPACKAGING DOCUMENTATION: Quantity Repackaged: Repackaging Tech Comments:	Attach Repackaged	d Sample	☐ Inspection of Product ☐ Inspection of Label ☐ Label Verified by: ☐ Clean Feed Table or Tubing for Liquid Repackaging ☐ Confirm Screen ☐ Repeater Pump Calibrated for Liquid Repackaging. Verified By: Repackaging Machine # Repackaging Tech Signature:
Difference in Quantity Explained VERIFICATION DOCUM Inspection of Product Inspection of Label	territoria de la composición del la composición del composición de la composición de la composición del composición del composición de la composición del la composición del composición d		Verification Tech Signature:
☐ Inspection of Blister ☐ Inspection of Foil ☐ 100% Verified Correct			
Verification Comments:			
OUALITY ASSURANCE ☐ Inspection of Product ☐ Inspection of Label ☐ Inspection of Blister ☐ Inspection of Foil ☐ Inspection of Completed			Quality Assurance Officer Signature:
QA Comments:			
SHIPPING DOCUMENTA ☐ Packaged per SOP ☐ Med Package Insert ☐ Invoice ☐ Package Slip	ATION:	Date and Time Shipped:	Shipping Tech Signature:
Shipping Comments:		 	

talah dawitu wa

Medication	Str	engtn	TRACKING#	
Manufacturer	Manufacturer	s Lot#	Manufacturer's Exp Date:	
Color/Form	ID Inscription_	· :	Customer	
Date Received	Quantity Receiv	red	Tech Signature	<u>.</u>
REPACKAGING DOCUMENTATION: Quantity Repackaged:	Attach Repackaged	l Sample	☐ Inspection of Product ☐ Inspection of Label ☐ Label Verified by: ☐ Clean Feed Table or Tubing for Liqu Repackaging ☐ Confirm Screen ☐ Repeater Pump Calibrated for Liquid Repackaging. Verified By: Repackaging Machine # Repackaging Tech Signature:	
Repackaging Tech Comments: Difference in Quantity Explaine VERIFICATION DOCULT Inspection of Product			Verification Tech Signature:	
☐ Inspection of Label ☐ Inspection of Blister ☐ Inspection of Foil ☐ 100% Verified Correct Verification Comments:	·			
OUALITY ASSURANCE ☐ Inspection of Product ☐ Inspection of Label ☐ Inspection of Blister ☐ Inspection of Foil ☐ Inspection of Complete			Quality Assurance Officer Signature:	
QA Comments;		•		
SHIPPING DOCUMENT Packaged per SOP Med Package Insert Invoice Package Slip Shipping Comments:	ATION:	Date and Time Shipped:	Shipping Tech Signature:	
ompping Commonis.		1		

1)	RUSTER (List or see attached Roster)	
2)		
3)		
4)		
Inspection Findings		· · · · · · · · · · · · · · · · · · ·
1)		_
2)	<u> </u>	
3)		
Statutas / Daniel-Mana 6		
Statutes / Regulations C A = 21 USC		
E = MGL 112 SEC 61	B = 247 CMR $C = 105 CMR$ $D = 94CL$	-
L - MGL 112 SEC 61	F = MGL C138 S 15L G = MGL C 138 S 30 A	
Licensee Signature:	200	7 1 7
Date:	License No: 20	2)/
Date.		
In continue to J. Cincol	.) Omeres	
Investigator's Signature	: Arew	
Date:	// 2/13/06	
•		
Supervisor's Signature_		
Date:		



The Commonwealth of Massachusetts Executive Office of Health and Human Services Department of Public Health Division of Health Professions Licensure 239 Causeway Street, 2nd Floor, Boston, MA 02114

MITT ROMNEY GOVERNOR

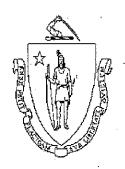
KERRY HEALEY LIEUTENANT GOVERNOR

TIMOTHY R. MURPHY PAUL J. COTE, JR. COMMISSIONER

JEAN K. PONTIKAS DIRECTOR

REQUEST FOR STAFF ASSIGNMENT

Send letter to complainant: Board to send letter to complainant of outcome:					
(To be filed Out by Requestor)					
BOARD NAME (entire):PHARMACY					
REQUESTED BY: James D. Coffey, Assoc. Dir. Date: 05/12/06					
APPROVED BY: DATE ASSIGNED:					
INVESTIGATOR ASSIGNED:					
Summary of Assignment:To conduct a controlled premises initial inspection of Ameridose,					
LLC proposed to be located at 50 Fountain Street, Framingham, MA 01702 pursuant to a NEW					
PREMISES application. The proposed Manager of Record of such pharmacy is Sophia Pasedis, R.Ph.,					
(Lic. No. 20217). The contact person for such inspection is Sophia Pasedis, R.Ph., MOR (508-656-2653)					
). The proposed opening date is not indicated on the application. (Investigator shall ensure that a					
designated counseling area is provided prior to related approval and that pharmacy is to comply with					
company policies for counseling. Please distribute the Boards Best Practices to the proposed Manager of					
Record. **It should be noted that the Board APPROVED the requested WAIVER 6.02(4).					
The "original" inspection report shall be forwarded to the Board to be attached to the application					
for licensure prior to granting a final permit number.					
(To Be Filed Out By Admin. Staff)					



The Commonwealth of Massachusetts

Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure
239 Causeway Street, 2nd Floor, Boston, MA 02114

Assignment Number:	BD Code:	FY:	NO:		
	(To be filed	l out by Inve	stigator)		
CO T. CAT					
Complainant Name:Phone #:					•
Subject of Assignment:					
Lic #:		·	•		
Home Address:					•
Phone #:					
•			•		
City, State, Zip:					
				-	
Business Name:					
Lic #:					
Address:				e e	
Phone:	<u> </u>		,		
City, State, Zip:	•				
DISPOSITION:					
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Tayran	rtigatars Tritials			When the state of	
	stigators Initials:			Lun	
Date Completed:	lime	Utilized:		hrs	
Additional Information atta	ached: □Yes □ N	0	•		· ·
Supervisor's signature:			Date:	. •	

Received

APR 25 2006

BOARD OF PHARMACY

Application for Registration to Manage and Operate a New Community Pharmacy

Ameridose, LLC 50 Fountain Street Framingham, MA 01702 508-656-2653 fax 508-872-0044



MITT ROMNEY GOVERNOR

KERRY HEALEY LIEUTENANT GOVERNOR

TIMOTHY R. MURPHY SECRETARY

PAUL J. COTE, JR. COMMISSIONER

JEAN K. PONTIKAS DIRECTOR

The Commonwealth of Massachusetts Executive Office of Health and Human Services Department of Public Health Division of Health Professions Licensure

Board of Registration in Pharmacy 239 Causeway Street, Suite 200, 2nd Floor Boston, MA 02114 (800) 414-0168 (office) / 617-973-0983 (fax) http://www.mass.gov/reg/boards/ph

APPLICATION FOR REGISTRATION TO MANAGE AND OPERATE A NEW COMMUNITY PHARMACY

- (1) In order to be registered by the Board to manage and operate a pharmacy or pharmacy department and be issued a permit to do so, the registered pharmacist who shall be responsible for the management and operation of the pharmacy or pharmacy department shall obtain and submit to the Board an application for registration to manage and operate a pharmacy or pharmacy department available from the Board. A completed application shall be:
 - (a) fully and properly completed and signed, under the penalties of perjury, by the pharmacist who is to manage and operate the pharmacy or pharmacy department;
 - (b) accompanied by a statement of the scheduled hours during which the pharmacy or pharmacy department is to remain open, including the time of opening and closing during regular business hours for each day of the week; Attachment "D"
 - (c) accompanied by an application, available from the Board, for a Massachusetts controlled substance registration;
 - (d) accompanied by an application, available from the Board, for a certificate of fitness, if applicable;
 - (e) accompanied by a check or money order made payable, in the proper amount, to the "Commonwealth of Massachusetts Board of Registration in Pharmacy"; and
 - (f) accompanied by any additional information as determined by the Board.
 - (g) accompanied by an official blueprint or certified architectural plans drawn to scale clearly designating both the prescription and patient consultation areas (pharmacy department shall be outlined in <u>RED</u>).
- (2) A completed application to operate a pharmacy shall include:
 - (a) a copy of the corporation's Articles of Organization, signed and sealed by the Secretary of State if the corporation is incorporated in the Commonwealth;

(b) a copy of the corporation's Foreign Corporation Certificate, signed and sealed by the Secretary of State pursuant to M.G.L. c. 181, § 4, if the corporation in incorporated in another state: (c) a statement of the name and address of each officer and director of the corporation and the position held; nla (d) the d/b/a name of the corporation; and (f) if the corporation is not publicly owned, the total amount and type of stock issued to each stockholder and the names and addresses of said stockholder(s). (3) The Board shall not register nor permit ownership of a pharmacy or pharmacy department by a practitioner with prescriptive privileges. (4) Before acting upon any application for registration to manage and operate a pharmacy or pharmacy department, the Board may require a hearing and, if requested to do so, the applicant shall personally appear before the Board to answer questions to enable the Board to determine that issuance of a permit would be in the best interests of the public health, welfare and safety as set forth in M.G.L. c. 112, § 39. (5) The Board may require an inspection of the pharmacy or pharmacy department before final approval of the application is granted. All proposed pharmacies and pharmacy departments shall comply with the following requirements: (a) No application for registration to manage and operate a pharmacy or pharmacy department shall be approved unless, upon inspection, the following is maintained on the pharmacy premises: 1. a current copy or electronic version of the Massachusetts List of Interchangeable Drugs (MLID), including the Orange Book, Additional List, Exception List, and the latest supplements thereto; 2. a current copy or electronic version (with quarterly updates) of a compendia appropriate to the practice setting approved by the pharmacist manager of record. 3. a current copy or electronic version of Board Regulations 247 CMR 1.00 et seg.; 4. a balance capable of accurately weighing quantities as small as 13 milligrams, which balance shall be tested and sealed by the state or local sealer of weights and measures annually; 5. the equipment necessary to conduct the practice of pharmacy according to the standards set forth by most current edition of the United States Pharmacopoeia: 6. prescription labels which bear the name and address of the proposed pharmacy; 7. appropriate sanitary appliances, including a suitable sink which shall be equipped for hot and cold running water and which shall be situated in or near the area in which

prescriptions are to be filled;

- 8. whenever applicable, at least one bound book for recording sales of controlled substances which may be sold over-the-counter without a prescription; and 9. whenever applicable, at least one book for recording sales of alcoholic beverages and signatures of the purchasers of these beverages. (b) There shall be within every pharmacy or pharmacy department a prescription area of not less than 300 square feet to accommodate the appropriate pharmaceutical equipment, apparatus, and supplies, and to facilitate the proper preparation and compounding of prescribed medications. This area shall provide for an arrangement and storage of drugs that is calculated to prevent their accidental misuse. (c) Any pharmacy or pharmacy department which establishes a central intravenous admixture service (CIVAS) shall, in addition to the 300 square feet required by 247 CMR 6.01(6)(b), provide for a separate room referred to as a "clean room" apart from all other areas of the pharmacy or pharmacy department. This clean room shall meet the following requirements: 1. There shall be a minimum working area of 72 square feet; 2. it shall be closed on all sides except for a door and an opening to allow for the passage of materials; 3. it shall have a laminar flow hood with either vertical or horizontal air flow; 4. the laminar flow hood standards of operation of HEPA (High Energy Particulate Air) filters and prefilters must be determined and certification shall be made annually by a Board-approved hood certification service; 5. the Board shall be notified before beginning operation of the clean room to verify hood certification; 6. the area of the clean room shall be under continual positive pressure unless the hood is self-venting; and 7. applications for construction of a pharmacy with a clean room received after September 30, 1996 shall show the clean room located directly adjacent to the prescription area/department. (d) Patient Consultation Area.
- stockroom or the prescription dispensing area.

 2. 247 CMR 6.01(5)(d) shall be effective for all new or relocating pharmacies on April 1, 2005. All existing pharmacies must comply with 247 CMR 6.01(5)(d) by January 1, 2007.

1. A pharmacy must provide a designated consultation area, with signage stating "Patient Consultation Area", designed to provide adequate privacy for confidential visual and auditory patient counseling. The private consultation area must be accessible by a patient from the outside of the prescription dispensing area without having to traverse a

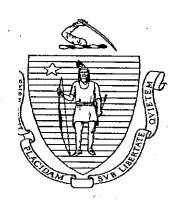
- (6) The Board shall issue a permit indicating the pharmacy or pharmacy department's registration number if the Board finds, in its reasonable discretion, that approving the application would be consistent with the best interest of public health, welfare and safety.
- (7) All fees submitted to the Board in connection with an application for registration to operate a pharmacy or pharmacy department, which are reviewed and acted upon by the Board, are nonrefundable.

Please be advised that no pharmacy and pharmacy department shall begin to operate until the application has been approved by the Board and: 1) the pharmacist Manager of Record has received from the Board a permit number to manage and operate the pharmacy and or pharmacy department, and 2) has received a controlled substances registration number.

For complete information regarding relocation regulations, please refer to 247 CMR 6.01 & 6.02. If additional information is necessary, please contact the Board office at (800) 414-0168.

To obtain a DEA number, please contact the Drug Enforcement Administration (DEA) office for an application. The address is: J.F.K. Federal Building

Drug Enforcement Administration Room E400 15 New Sudbury Court Boston, MA 02203-0131 (617) 557-2200



The Commonwealth of Massachusetts
Executive Office of Health and Human Service
Department of Public Health
Division of Health Professions Licensure

Board of Registration in Pharmacy 239 Causeway Street, Suite 200, 2nd Floor Boston, MA 02114 (800) 414-0168 (office) / 617-973-0983 (fax) http://www.mass.gov/reg/boards/ph

APPLICATION FOR A NEW STORE

MTT ROMNEY GOVERNOR

KERRY HEALEY
LIEUTENANT GOVERNOR

TIMOTHY R. MURPHY SECRETARY

PAUL J. COTE, JR. COMMISSIONER

ACCEPAGE KAS

APR 25 2006

BOARD OF PHARMACY

I hereby apply for a permit to operate a store for the transaction of retail drug business in accordance with the provisions of Chapter 112, General Laws.

\$351.00 licensure / application fee. Make check or money order for \$351.00 payable to the Commonwealth of Massachusetts. This fee is non-refundable.

- 1. Legal Name of Business. Ameridose, LLC
- 2. Full Business Address (Street Address, City, State and Zip). 50 Fountain Street, Framingham, MA 01702
- 3. Area Code and Telephone Number. 508-656-2653
- 4. All trade or business names ("D.B.A." names) used by same Corporation or by License. Ameridose, LLC
- 5. Type of ownership or operation (i.e., sole proprietorship, partnership, corporation). Limited Liability Company (LLC)

If corporation, please submit articles of corporation. Please see Attachment "A"

5. Names(s) and Social Security Number(s) of the owner(s) and/or operator(s) of the licensee. Please indicate type of ownership - Partnerships: the name of each partner and name address of partnership;

Corporations: the name and title of each corporate officer and director, the corporate names, name and address of parent company, if any, and the State of incorporation; Sole Proprietorship: the name of the sole proprietor and the address of the business entity. Please see Attachment "B"

- 7. Name of registered pharmacist charged with the management of the pharmacy. Sophia Pasedis, RPh, PharmD.
- 8. Registration number of above manager. 20217
- 9. Name(s) and registration number(s) of staff pharmacist(s) employed at pharmacy. Sophia Pasedis, RPh, PharmD.
- 10. Have any of the applicant(s) and/or managers-in-charge had: 1) any convictions related to the distribution of drugs (including samples); 2) any felony convictions; 3) any suspension(s) or revocation(s) or other sanction(s) by federal, state or local governmental agency of any license or registration currently or previously held by the applicant or license for the manufacture, distribution, or dispensing of any drugs, including controlled substances? NO

Have any applications for licensure been denied by any federal or state agency including any state board of pharmacy? NO

List and explain. Attach additional sheets if necessary. N/A

- 11. The applicant/licensee must notify the Board in writing of any changes in ownership or management within thirty (30) days of such change(s).
- 12. Social Security Number (Mandatory).

 Pursuant to M.G.L. c. 62C, s. 47A, the Division of Registration is required to obtain your social security number and forward it to the Department of Revenue. The Department of Revenue will use your social security number to ascertain whether you are in compliance with the tax laws of the Commonwealth.

List any licenses/certifications you hold in the United States or any country or foreign jurisdiction and the state/jurisdiction from which the license/certification was originally issued. Please attach a certificate of standing from each state or jurisdiction in which you are licensed/certified, indicating the status of your license and any relevant disciplinary information. Massachusetts Registered Pharmacist License #20217, Attachment "C."

- 14. Has any disciplinary action been taken against you by a licensing/certification board located in the United States or any country or foreign jurisdiction? Yes: ☐ No: X

 If yes, please state the details (use a separate sheet if necessary). N/A
- 15. Are you the subject of pending disciplinary actions by a licensing/certification board located in the United States or any country or foreign jurisdiction? Yes: □ No: X

 If yes, please state the details (use a separate sheet if necessary). N/A
- 16. Have you ever voluntarily surrendered or resigned a professional license to a licensing/certification board in the United States or any country or foreign jurisdiction? Yes: □ No: X If yes, please state the details (use a separate sheet if necessary). N/A
- 17. Have you ever applied for and been denied a professional license in the United States or any country or foreign jurisdiction? Yes:

 No: X

 If yes, please state the details (use a separate sheet if necessary). N/A

18. Pursuant to Board Regulations at 247CMR δ 6.01(3), The Board shall not register nor permit ownership of a pharmacy or pharmacy department by a practitioner with prescriptive privileges. By signing this application the applicant certifies that none of the owners, directors or officers have prescriptive privileges.

Affidavit (must be completed and notarized)

Pursuant to M.G.L. c. 62C, s. 49A, I certify under the penalties of perjury that I, to the best of my knowledge and belief, have filed all state tax returns and paid all state taxes required under law.

The applicant certifies that each person employed in any prescription drug distribution activity has the education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety, and security will at all times be maintained as required by law.

I hereby state that I am the person authorized to sign this application for all licensure; that all statements are true and correct in all respects and are made under the penalties of perjury.

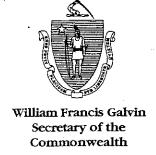
Signature of pharmacist who is to nanage the pharmacy or pharmacy department

April 5, 2006
Date

Social Security Number of the Manager of Record

To be completed by the Board: Check \$ 357

Sworn and subscribed before me this	144	<u></u> day	of AC	ril 2006
My commission expires 12/31	lacio.	Careel	Lee X	leever.
	-	1	Notary Publ	ic
				,



The Commonwealth of Massachusetts

Secretary of the Commonwealth

State House, Boston, Massachusetts 02133

April 10, 2006

TO WHOM IT MAY CONCERN:

I hereby certify that a certificate of organization of a Limited Liability Company was filed in this office by

AMERIDOSE, LLC

in accordance with the provisions of Massachusetts General Laws Chapter 156C on February 8, 2006.

I further certify that said Limited Liability Company has filed all annual reports due and paid all fees with respect to such reports; that said Limited Liability Company has not filed a certificate of cancellation or withdrawal; and that, said Limited Liability Company is in good standing with this office.

I also certify that the names of all managers listed in the most recent filing are: GREGORY CONIGLIARO, BARRY J. CADDEN

I further certify, the names of all persons authorized to execute documents filed with this office and listed in the most recent filing are: GREGORY CONIGLIARO, BARRY J. CADDEN

The names of all persons authorized to act with respect to real property listed in the most recent filing are: GREGORY CONIGLIARO, BARRY J. CADDEN



In testimony of which,

I have hereunto affixed the

Great Seal of the Commonwealth
on the date first above written.

William Travino Galicin

Secretary of the Commonwealth

Processed By:MT

AMERIDOSE, LLC CERTIFICATE OF ORGANIZATION

FEB 3 8 2006

SPORE AND LETTER OF THE SECRET

Pursuant to the provisions of the Massachusetts Limited Liability Company Act (the "Act") the undersigned hereby certifies as follows:

- 1. Name of the Limited Liability Company. The name of the limited liability company formed hereby (the "Company") is Ameridose, LLC.
- 2. Office of the Limited Liability Company. The address of the office of the Company in the Commonwealth required to be maintained by Section 5 of the Act is 50 Fountain Street, Framingham, MA 01702.
- 3. <u>Agent for Services of Process.</u> The name and address of the resident agent for services of process for the Company is Gregory Conigliaro, 50 Fountain Street, Framingham, MA 01702.
 - 4. <u>Date of Dissolution.</u> The Company is to have no specific date of dissolution.
 - 5. Manager. The Managers are:

Gregory Conigliaro 50 Fountain Street Framingham, MA 01702

Barry J. Cadden 50 Fountain Street Framingham, MA 01702

- 6. <u>Execution of Documents.</u> Either Manager is authorized to execute any documents to be filed with the Secretary of State of the Commonwealth of Massachusetts.
 - 7. Business of the Company.
 - (a) To provide unit dose repackaging services;
 - (b) To exercise all other powers necessary to or reasonably connected with the Company's business that may be legally exercised by limited liability companies under the Act; and
 - (c) To engage in all activities necessary, customary, convenient, or incident to any of the foregoing.
 - 8. Execution of Documents Relating to Real Property. Either Manager is authorized

to execute, acknowledge, deliver and record any recordable instrument on behalf of the Company purporting to affect any interest in real property, whether to be recorded with a registry of deeds or a district office of the Land Court.

IN WITNESS WHEREOF, the undersigned hereby affirms under the penalties of perjury that the facts stated herein are true, this 6 day of February, 2006.

Chego Conigliaro
Gregor Conigliaro

Chaole/Moucher	#	89	
Check/Voucher	#	87	

The Commonwealth of Massachusetts Limited Liability Company (General Laws, Chapter 156C)

989316

SECRET: "Y OF THE	2006 FEB -8 PH 2: 42	הטוצועות זייויי טערישטט
SEC	2006	7.2.2.A

Filed this 8 day February, 2006

aple Frein Galuck

William Francis Galvin Secretary of the Commonwealth

Name	JONATHAN	Û	TAMKIN	
		•	•	
Phone	617	964.	2501	

Attachment "B"

Ameridose, LLC

50 Fountain Street, Framingham, MA 01702

Tel: 508-656-2653 Fax: 508.872-0044

TYPE OF OWNERSHIP

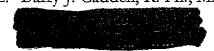
Limited Liability Company
Organized in the Commonwealth of Massachusetts

COMPANY OPERATORS/MANAGERS

1. Gregory A. Conigliaro, Manager



2. Barry J. Cadden, R. Ph., Manager



LLC OWNERS

1. Carla R. Conigliaro
Ownership: 55% membership interest



2. Barry J. Cadden, R. Ph.
Ownership: 17.5% membership interest

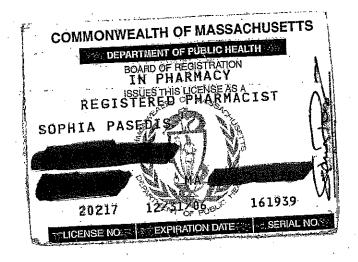


3. Lisa M. Conigliaro Cadden, R. Ph. Ownership: 17.5% membership interest



4. Gregory A. Conigliaro
Ownership: 10% membership interest

Attachment "C"



DPH CONTROL# 0259680 IMPORTANT

If this license becomes lost or destroyed, notify your Board at the: Department of Public Health, 239 Causeway St., 5th Floor, Boston, MA 02114

the proper mailing of your next Renewal Application. Always the proper mailing of your next Renewal Application. Always refer to your license number when corresponding with your aboard. This license is subject to the provisions of the General Laws as amended. It is a privilege, and cannot be General Laws as amended. It is a privilege, and cannot be loaned or assigned to any other entity. Keep this license on your person, posted, or as required by law.

Please visit our web site at: http://mass.gov/dph/boards



The Commonwealth of Massachusetts

Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure

Attachment "D"

MITT ROMNEY GOVERNOR

KERRY HEALEY
LIEUTENANT GOVERNOR

TIMOTHY R. MURPHY SECRETARY

PAUL J. COTE, JR. COMMISSIONER

JEAN K. PONTIKAS DIRECTOR Board of Registration in Pharmacy 239 Causeway Street, Suite 200, 2nd Floor Boston, MA 02114 (800) 414-016§ (office) / 617-973-0983 (fax) http://www.mass.gov/reg/boards/ph

PHARMACY HOURS

Name of Store: Ameridose, LLC

Street: 50 Fountain Street

City or Town: **Framingham** Zip Code: **01702**

Phone Number: 508-656-2653

	Open	Close	Hours
Monday	8:30 am	5:30 pm	9
Tuesday	8:30 am	5:30 pm	9
Wednesday	8:30 am	5:30 pm	. 9
Thursday	8:30 am	5:30 pm	9
Friday	8:30 am	5:30 pm	. 9
Saturday	Closed	Closed	0
Sunday	Closed	Closed	0

Total Hours Per Week:

April 14, 2006

Date

Signature of Manager of Record or Duly Authorized Representative

Sophia Pasedis, RPh, PharmD.

Print Full Name

Application for Certificate of Fitness

Received

APR 25 2006

BOARD OF

Ameridose, LLC 50 Fountain Street Framingham, MA 01702 508-656-2653 fax 508-872-0044



MITT ROMNEY GOVERNOR

KERRY HEALEY LIEUTENANT GOVERNOR

TIMOTHY R. MURPHY SECRETARY

PAUL J. COTE, JR. COMMISSIONER

JEAN K. PONTIKAS DIRECTOR

The Commonwealth of Massachusetts

Executive Office of Health and Human Services Department of Public Health Division of Health Professions Licensure

Board of Registration in Pharmacy 239 Causeway Street, Suite 200, 2nd Floor Boston, MA 02114

(800) 414-0168 (office) / 617-973-0983 (fax) APR 25 2006

http://www.mass.gov/reg/boards/ph

BOARD OF PHARMACY

Received

APPLICATION FOR A CERTIFICATE OF FITNESS Manager of Record Must Complete Application. Fee: \$120.00

I, Sophia Pasedis (name), at 508-656-2653 (telephone), of 50 Fountain Street (street address), Framingham (city). MA (state), 01702 (zip code), a registered pharmacist, certificate number 20217 being now actively engaged in conducting a retail drug business as sole owner or Manager of Record for the firm / corporation of Ameridose, LLC do hereby apply for CERTIFICATE OF FITNESS, claiming to be a proper person to be entrusted with the authority to:

- 1) Use alcohol for the manufacture of United States Pharmacopeia and National Formulary preparations and all medicinal preparations unfit for beverage purposes.
- 2) Sell, in accordance with the laws of the Commonwealth, alcohol and alcoholic liquors, and that the public good will be promoted by the granting of such license.

I have \$0 (give dollar amount) invested in said retail business and will comply with the laws of this Commonwealth and the regulations of the Board relating to the use and sale of the alcohol and alcoholic liquors.

I certify that I have not been convicted of a violation of said laws within one year prior to the date of this application.

I agree to notify the board at once if I cease to conduct the retail drug business at the above location and will return the certificate issued thereon.

Date: April 14, 2006

Please submit non-refundable check or money order for \$120.00 payable to the Commonwealth of Massachusetts.

· · · · · · · · · · · · · · · · · · ·	- Please do not write below this line -	
Check / J-D Number 980	M.O	

Application for Mass. Controlled Substance Registration

Received APR 25 2006 BOARD OF PHARMACY

Ameridose, LLC 50 Fountain Street Framingham, MA 01702 508-656-2653 fax 508-872-0044



MITT ROMNEY GOVERNOR

KERRY HEALEY
LIEUTENANT GOVERNOR

TIMOTHY R. MURPHY SECRETARY

PAUL J. COTE, JR. COMMISSIONER

JEAN K. PONTIKAS DIRECTOR

The Commonwealth of Massachusetts

Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure

Board of Registration in Pharmacy 239 Causeway Street, Suite 200, 2nd Floor Boston, MA 02114 (800) 414-0168 (office) / 617-973-0983 (fax) Received http://www.mass.gov/reg/boards/ph

BOARD OF PHARMACY

APPLICATION FOR MASS. CONTROLLED SUBSTANCE REGISTRATION FEE: \$151.00

Cash	Check # / E/			
No. 1136	Date 47/06	M.O		
	Please do not write above thi	s line		
I here apply for Registration un	der Mass. Controlled Substances A	Act-M.G.L. 94C Sec	tion 7.	
Applicant Name (corporation)	Ameridose, LLC			
Business Address:	50 Fountain Street (No. and Street)			
•	Framingham, MA 01702			
	(City or Town)	(State)	(Zip Code)	
Registration Classification: (a) X	Retail Drug Store (b)	Wh	olesale/Mfg/Dist.	
(c)	Hospital/Clinic/Inst. (d)		luclear	

FEIN # 20-4253511

Schedule II (X) Non-Narcotic (X) Narcotic	Schedule III (X) Non-Narcotic (X) Narcotic		X) Schedule VI	
Current drugstore p	ermit No. pending	Current Wholesale Druggist Lic	ense No. n/a	
Signature of Applie	cant Me	& a Confliano ug	L.	
5 11	00	Owner of facility must sign app		

Please submit check or money order for \$151.00 payable to the Commonwealth of Massachusetts.

WARNING:

Drug Schedule

In accordance with Chapter 94 M.G.L. Sec 13, the Board of Registration in Pharmacy in the case of a retail drug business or wholesale druggist, may suspend or revoke a registration to manufacture, distribute, dispense or possess a controlled substance after a hearing pursuant to the provisions of Chapter 34A and upon finding that the registrant has furnished false or fraudulent information in any application filed under the provisions of Chapter 94C.

Ameridose, LLC

50 Fountain Street, Framingham, MA 01702 508-656-2653, fax 508-872-0044

April 25, 2006

Charles R. Young

Executive Director

Received

Massachusetts Board of Registration in Pharmacy

239 Causeway St

APR 25 2006

Boston, MA 02113

4FK & J 2000

Dear Mr. Young,

BOARD OF PHARMACY

Please find attached our Application for Registration to Manage and Operate a New Community Pharmacy as well as supporting applications and drawings.

We are confident that our services will fill an urgent need in the Massachusetts healthcare environment and enhance public health, welfare and safety.

nflaro

I may be reached at 508-656-2633 should you require further information. Thank you for your consideration.

Sincerely,

AMERIDOSE, LLC.

Gregory A. Conigliaro

Manager

Received

APR 25 2006

BOARD OF

Petition for a Waiver of the Provisions of 247 Licensure of a Pharmacy and or Pharmacy Department

Ameridose, LLC 50 Fountain Street Framingham, MA 01702 508-656-2653 fax 508-872-0044



MITT ROMNEY GOVERNOR

KERRY HEALEY LIEUTENANT GOVERNOR

TIMOTHY R. MURPHY SECRETARY

PAUL J. COTE, JR. COMMISSIONER

JEAN K. PONTIKAS DIRECTOR

The Commonwealth of Massachusetts

Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure

Board of Registration In Pharmacy
239 Causeway Street, Suite 200, Boston, MA 02114.
(800) 414-0168 (office) / 617-973-0983 (fax) eceived
http://www.mass.gov/reg/boards/ph

APR 25 2006

BOARD OF PETITION FOR A WAIVER OF THE PROVISIONS OF 247 HARMACY LICENSURE OF A PHARMACY AND OR PHARMACY DEPARTMENT

Application to be completed by the registered pharmacist who is or shall be responsible for the management and operation of the pharmacy and or pharmacy department.

Pursuant to 247 CMR (14.01), I hereby apply for a special or limited use pharmacy or pharmacy department permit because the type of pharmacy practice is of a special, limited or unusual nature as compared to regular pharmacy services.

Name of pharmacy and or pharmacy department: Ameridose, LLC

Location: 50 Fountain Street, Framingham, MA 01702

Phone number: 508-656-2653

Contact Person: Sophia Pasedis, RPh, PharmD

Please use separate sheets to complete the following and attach sheets to application:

- 1. List the regulatory requirements(s) for which a waiver is requested and provide an explanation as to why each regulation should not apply to the pharmacy/pharmacy department.
- 2. Explain the compelling public interest that would be served by the granting of a waiver.
- 3. Explain why adherence to the regulation(s) would be impractical and unduly burdensome.
- 4. Include a comprehensive statement of the policies and procedures of the proposed operation, including safeguards to protect the public health, welfare and safety.

Before acting upon any petition the Board may require the applicant to personally appear before the Board to answer questions that would enable the Board to determine that the issuance of a permit would be in the best interest of the public health, welfare and safety and adherence to 247 CMR would be unreasonable.

Upon the granting of a waiver and issuance of a special or limited-use permit, the Board will issue a written finding that recites the specific Board regulations(s) which are being waived, the reasons the Board is waiving the regulation(s) at issue, and lists and contingent restrictions under which the pharmacy or pharmacy department may operate.

I declare that the statement and answered herein-contained are true and are made under the pains and penalties of perjury.

Signature of pharmacist manager of record

Date

Petition for a Waiver of the Provisions of 247 Licensure of a Pharmacy and or Pharmacy Department

1. List the regulatory requirements(s) for which a waiver is requested and provide an explanation as to why each regulation should not apply to the pharmacy/pharmacy/epartment.

247 CMR 6.02 (4) — The pharmacy or pharmacy department shall maintain on premise at all times a sufficient variety and supply of medicinal chemicals and preparations which are necessary to compound and dispense commonly prescribed mediations in accordance with the usual needs of the community

We are requesting a waiver to the above provision. It is our opinion that Ameridose's pharmacy practice is of a special limited or unusual nature compared to the regular retail pharmacy.

2. Explain the compelling public interest that would be served by the granting of a waiver.

Ameridose serves the public interest by offering high quality sterile IV admixtures, TPNs and repackaging services to hospital pharmacy departments, clinics and physician's offices: our community. Ameridose will not service the public directly. We do not intend to maintain or dispense all standard prescription medications as may be found in a typical retail pharmacy setting. Rather, we will be a conduit to improved patient care and safety by offering high quality medications to the above entities subject to factors such as beyond use dating and other safety considerations.

The need for our services has spawned from the rapidly changing regulatory environment which the pharmacy departments and clinics are now tasked to manage, including JCAHO and USP requirements. As a result, hospitals and clinics are seeking to outsource these critical services. Our trained registered pharmacists and certified technicians will be able to concentrate on preparing the highest quality medications, while our clients will be freed up to focus on the needs and care of their patients, which is what they do best. The services provided by Ameridose to healthcare institutions, clinics and physicians across the Commonwealth is urgently needed and will absolutely enhance public health, welfare and safety.

3. Explain why adherence to the regulation(s) would be impractical and unduly burdensome.

The regulation in question is impractical and unduly burdensome in this instance - we will be unable to offer all prescription medications typically found in a retail pharmacy and/or available from a wholesaler. Due to the specialized nature of the equipment, facilities and personnel required to provide our unique IV admixture, TPN and repackaging services, the maintenance and dispensing of typical manufactured medications would be incongruent with our mission.

It should be noted, that there are approximately nineteen (19) standard retail pharmacies currently located in Framingham, MA as well as several wholesalers in state. As such, medications required by the public that we do not plan to dispense at Ameridose are readily available in the local community.

4. Include a comprehensive statement of the policies and procedures of the proposed operation, including safeguards to protect the public health, welfare and safety.

All of our high quality sterile IV admixtures, including TPNs, will be prepared in a controlled environment, using the latest Laminar Flow Technology contained within a state-of-the-art ISO 6. Cleanroom.

Ameridose has developed and shall maintain a complete set of Standard Operating Procedures (SOPs). Chapters include: Guidelines for Preparations, Facilities and Cleaning Procedures, Equipment and Supplies, Pharmacy Practice, Sterilization and Depyrogenation and Quality Assurance/Quality Control. All of these SOPs shall be reviewed and followed by all pharmacists and technicians on an ongoing basis. Ameridose has developed and shall maintain a company-wide Quality Assurance Program. This program shall insure real-time improvements to our operations on a continual basis.

Ameridose's "above and beyond mentality" shall insure that safeguards are always in place to protect the public health, welfare and safety.